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Version History

Version date	Version	Author	Reason for change
02-DEC-2022	V1.0	Tiago Barrosa Anjos	Initial Document
03-FEB-2023	V2.0	Tiago Barrosa Anjos	Document updated with the new section "High-level explanation of the AMS Hub and its specifications section", and all MAH processes in the section "The MAH process and the EAMS"
25-MAY-2023	V3.0	Tiago Barrosa Anjos	Document updated after the input from stakeholders representatives in the following sections: "3.3. Out of scope of guidance" and "3.4. High-level process"
17-AUG-2023	V4.0	Tiago Barrosa Anjos	The document was updated with some formatting issues in chapter 3 and correction of typos. Clarification on Chapter 5 added regarding the "MAH Workflow Indicator".



			
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1. Definitions

Table 1: Definitions

Term/Acronym	Definition
Alert	An alert is an exception which is deemed as critical and therefore should be notified. Alerts, therefore, produce notifications.
Alert ID	An Alert ID is an identifier for a single instance of an alert. One pack can be associated with one or many Alert IDs. This term is commonly called by "Unique Alert Return Code" (UPRC), which is physically related to a pack as part of a returns process.
EAMS	The European Alert Management System that consists of the AMS Hub, a set of National AMSs, and one or multiple AMS MAH systems.
AMS MAH	A system that an MAH uses to process the alerts relevant to him. The MAH uses this system to interact with the AMS Hub.
AMS Hub	Alert Management System that is hosted in the EU Hub and accessible via National systems for end-users and EU Hub for MAHs.
API	Application Programming Interface. An agreed protocol that allows client and server software to communicate through requests and responses.
Delegated Regulation	Commission Delegated Regulation (EU) 2016/161 as amended.
EMVO	European Medicines Verification Organisation.
EMVS	European Medicines Verification System.
End-Users	Pharmacy, Hospital, Wholesaler or any other person authorised or entitled to supply medicinal products to the public in accordance with the Delegated Regulation.
National AMS (NAMS)	A national system that is tasked to connect the different national users to the AMS Hub and to support the alert investigation of these users.
NCA	National Competent Authority is an entity which supervises the functioning of any repository physically located in their territory. NCAs are ultimately responsible for the decisions made if an alert is confirmed and if it has an impact on public health.

			
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Term/Acronym	Definition
NMVO	National Medicines Verification Organisation.
NMVS	National Medicines Verification System.
OBP	On-Boarding Partner. A company or Organisation that represents the affiliated entities that hold marketing authorisation for products for which the MAH uploads product and pack data to the EU Hub. For practical reasons, the document mentions the MAH instead of the MAH. It is understood that in some member states the legally responsible entity is the MAH.
User	User is an entity which can interact with the EAMS.

2. Purpose

This is a living document and will be updated when new information regarding alert management is available and as soon as learnings become available from applying this process in practice.

This document at hand explains how the European Alert Management System (EAMS) can be used by MAHs to support alert handling as described in [EMVO-00306 Best Practice on Alert Handling](#) which sets out decision trees for investigation of alerts, defines the role of end-users, MAHs, NMVOs and EMVO and describes communication channels between them, including alert management systems where they are in place.

The processes described in the present document aim at facilitating communication between all actors within the alert investigation process. Please note that in some countries, these guidelines may not be applied due to country-specific requirements (see also [Appendix A – Country Specifications per action](#)).

3. High-level principles of the EMVO-00306 Best Practice on Alert Handling

AMS: Alert Management System

DR: [Commission Delegated Regulation on safety features \(EU\) 2016/161](#)


EMVS: European Medicines Medicines Verification System which comprises EU Hub and all national systems (NMVS) connected to EU-Hub

End-user: Pharmacy, hospital, wholesaler or any other person authorised or entitled to supply medicinal products to public connected to an NMVS

IMT alerts: Alerts generated when scanning packs sourced from other EU markets for which there is no data in the IMVS. An intermarket transaction (IMT) is triggered to allow the barcode data to be checked against data held in the NMVS for the originating market

MAH: For purpose of guidance, term 'MAH' is broadly construed and also covers:

- OBP (onboarding partner) who manages EMVS data upload on behalf of MAH

			
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- Any party who acts on behalf of MAH in placing their product(s) on market in a member state, including a local affiliate or representative
- Any other party to whom MAH has delegated responsibility for any of its obligations under the DR
- Authorised manufacturer(s) of MAH's product(s)

NCA: National competent authority

3.2. Principles underpinning guidance

- Guidance describes process for handling level 5 alerts which generate alert ID in EMVS
- Designed for when system is at steady state (alert rate in the region of $\leq 0.05\%$ or lower) which means:
 - Scanner & software issues are uncommon
 - MAH data errors are minimised
 - No. of alerts to be investigated is low
- EMVS principles of data ownership and end-user anonymity vis-à-vis MAHs are respected
- Objectives include:
 - Ensuring that alerts are quickly investigated to rule out technical or procedural root cause so that the pack may be supplied to a patient
Empowering end-users to supply packs if they can identify a root cause at their side (and where possible fix it, e.g. scanner issue) without having to wait for go ahead from NMVO or MAH

3.3. Out of scope of guidance


- Exceptions which are not level 5 alerts, e.g. 'product not found' A1 alerts
- Process for NCA investigation of alerts
- Alert prevention activities
- Process for verifying anti-tampering devices (ATD)
- Process for damaged packs which cannot be authenticated
- Process for unexpected pack status upon verification

3.4. High-level process

Important note:

Please note that national authorities shall be informed about a suspected falsification as soon as technical reasons for an alert can be ruled out to be in line with the current interpretation of the legislation by the Commission. Investigation details can be exchanged to rule out any technical or procedural reason; however, before a pack is returned to the MAH for analysis, the NCA should be informed.

- End-users and MAHs initiate simultaneous investigation of alerts generated when end-users scan packs
- MAHs also investigate alerts generated from their own transactions
- End-users look for errors on their side - technical errors (scanners), procedural errors (e.g. double decommision) and IT errors (e.g. software)
- MAHs look for data issues and issues with EU Hub or NMVS where alert was generated
 - Note: MAHs not required to investigate certain categories of alerts generated at end-user locations – as these are typically due to end-user error - unless asked to do by NCA, NMVO or end-user


			
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- A7/A24 alerts (pack already decommissioned – mostly due to repeat scanning of packs)
 - A68 alerts (batch number mismatch – most commonly arises due to scanner or software issue)
- MAH expected to provide feedback within 2 working days & further progress reports if alert not resolved
- End-user withholds pack from saleable stock until:
 - They identify and fix (if possible) end-user error, e.g. scanner issue, the pack is successfully verified;
 - If there is no end-user error:
 - MAH confirms they have identified root cause (e.g. data issue, system issue) & if possible fixed root cause (e.g. by uploading data) **or**
 - MAH requests pack to be returned for analysis on basis that end-user error, data and system issues have been ruled out
 - MAH may request photo of pack from end-user prior to requesting that pack is returned
- If no feedback from end-user or MAH within 2 working days of alert being generated, NMVO steps in to check if root cause has been established:
 - If **YES**, informs the other party
 - If **NO**, requests that alert is investigated and provides whatever support is required to ensure root cause is identified. If either party fails to provide any essential info. or assistance, NCA may be requested to intervene with them
- Pack is a suspected falsification if all possible technical or procedural root causes have been ruled out following investigation by MAH, end-user and NMVO, including analysis of pack
- MAH notifies NCA and EMA (for centrally authorised products) of suspected falsification according to applicable national or European legislation / regulations and the NMVO
- NMVO ensures that NMVO, NCA, EMA and Commission have been notified of suspected falsification (if not already done by MAH where applicable)
- EMVO:
 - Ensures that all EU Hub alerts reported to MAHs and not notified to NMVOs are investigated
 - Provides support to NMVOs in investigation of alerts
- NMVOs monitor their systems for large numbers of alerts, unusual patterns of alerts by product or end-user, and contact end-user or MAH or FMD software provider to take action to prevent further alerts
 - Objective is to ensure that issues leading to large numbers of alerts in given end-user location or with a particular batch are quickly identified and resolved with support from NMVO
- Best practice also describes process for investigation of IMT alerts – investigation is initiated in market where pack is scanned, and NMVO in market where data is held provides support

4. Audience

This handbook is aimed at MAHs using the EAMS and who have procedures in place that enable them to comply with their respective responsibilities in relation to alerts generated in the EMVS.

As per the EMVO-00306 Best Practice on Alert Handling, an alert must be investigated by the relevant users to rule out technical or procedural root causes, such as issues with the EMVS, data upload, data quality, incorrect end-user scanning or other similar technical issues. While this is basically a task for

			
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all users, this handbook focuses on MAH activities. When all above mentioned root causes are ruled out, it is then considered a suspected falsifications and reported accordingly.

The objective of this document is to support MAHs in alert management. Notwithstanding, NMVOs and end-users also participate in the investigation of the alerts according to the [EMVO-00306 Best Practice on Alert Handling](#).

The general principle is that the NMVO does not actively intervene within the first 2 working days¹ of an alert being generated to allow the end-user and MAH to undertake their investigations. If an alert appears unusual or there are large number of alerts (e.g. per product or location), and the NMVO believes it requires immediate investigation, the NMVO may intervene sooner. Additionally, NMVOs must support communications between end-users and MAHs about alerts to maintain end-user anonymity if there is no AMS to facilitate direct (anonymous) communications between them.

If it is not possible to complete the investigation of an alert once the end-user and/or the MAH fail to provide any essential information or assistance the NMVO may request the NCA to intervene with the relevant user(s).


5. High-level explanation of the AMS Hub and its specifications

This section provides an overall description of the AMS Hub concepts, which may be necessary to comprehend the document at hand. It will only provide an high-level overview of the concepts one can found within the EAMS. The section **The MAH process and the EAMS** will provide you with a detailed view on the process. For now, please note that investigating an alert within the EAMS consists of providing the following actions:

1. Provide the **User Specific Workflow Indicator**, where the users will update the alert with the information gathered on their side regarding their findings. In the MAH case, this would be the "MAH Workflow Indicator". This action allows to set the **User Specific Workflow Indicator**. That means we will have an:
 - a. MAH Workflow Indicator (please note that, as an MAH, the connection with the EAMS can be done via the AMS Hub directly or through the NAMS. When using the AMS Hub connection, the MAH is represented by the OBP, and therefore this attribute is "OBP Workflow Indicator". In hybrid cases, where the OBP connected to the AMS Hub and the MAH connected to the NAMS are both using the system, only one action shall be required. In case of contradictory responses, this shall be resolved at the MAH and OBP level, as none of the answers prevail);
 - b. End-user Workflow Indicator;
 - c. NMVO Workflow Indicator;

The section **User Specific Workflow Indicator** will provide you with the full details regarding this.

¹ These responsibilities may differ between countries as some national procedures have to be followed. National procedures can be found in the [Appendix A – Country Specifications per action](#).

			
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2. The users can also change the **Alert Status**, when the information available is sufficient to set a global status of the alert. Each alert shall have one single **alert status** at the time which works as the global/overall status The existing statuses are:
 - a. New
 - b. Under Investigation
 - c. Closed
 - d. Escalated

The section **Change the Alert Status** will provide you with the full details regarding this.

3. The users may also need to **send messages** when extra information is required, or to share any other information necessary to investigate the alert appropriately (e.g. a picture of the pack). This functionality is also further described later on in this document.


It is also expected that from an MAH perspective the different actions are taken in a certain order. To understand better the following points, it is recommended to [EMVO-00306 Best Practice on Alert Handling](#) Please bear in mind that the detailed process can be found later in this document under the section **The MAH process and the EAMS**.

1. Initially, the MAH will start the investigation and provide the **MAH investigation status**. As per the above, here, the MAH will indicate whether or not the root cause was found at their end. (please note that the investigation from the end-user may also be running in parallel).
2. The MAH shall evaluate the results of its investigation and update the alert with this information.
3. The next step consists of answering the question "Did the MAH find the root cause?"
4. If the root cause has not to be found, and no technical or procedure root cause was ruled out, it will still be necessary for the end-user and the NMVO to finalise their investigation. Therefore, the following question can be raised "Has the MAH found the root cause of the alert on their side?"
 - 4.1. When the MAH has not found any technical or procedural error, but the inputs either from the end-user or the NMVO are still missing, then there is nothing else to do at the moment and it is expected that the end-user and/or the NMVO continue the investigation on their end. Therefore, the process ends here for the MAH.
5. When the MAH is the last stakeholder providing their input, then, at this stage, it has the full picture and inputs from all stakeholders. At this stage, all stakeholders ruled out any technical and/or procedural errors. Therefore, this shall be one of those cases where alerts need to be escalated. It is expected thus that the MAH changes the **alert status** to "Escalated".
6. When the MAH has found an error and has fixed it, then it can communicate with the other parties and change the **alert status** to "Closed"

Please note that, in specific scenarios, alerts can be "Reopened" for further investigation. This case will be treated as an exception. It is the responsibility of the entity which reopened it to get in touch with other parties to seek any additional information required from the original investigation.

5.1. User Specific Workflow Indicator

The User Specific Workflow Indicator (also known as "Investigation status") allows each user to inform other parties about the status of their activity on the investigation. For instance, as a MAH, it might be relevant to inform the NMVO and the end-user that the investigation is still ongoing or, on the other hand, that the investigation has been completed and no root cause was identified on their side. Therefore, the EAMS allows each user to set different statuses. There are four different indicators, and their meaning can be found below:

			
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- **Blank;** This is the default value and means that the alerts have not been worked on by the corresponding user.

None of the participants of an alert investigation can revert the User Specific Workflow Indicator to "blank".

- **Investigation pending;** This is to be used by the user when the investigation has started to let other parties know that they are still investigating.
- **No root cause on my side;** This is to be used by the user when the investigation has been completed and no root cause was identified on their side.
- **Root cause is on my side;** This is to be used by the user when the investigation has been completed and root cause was identified on their side.

The following table illustrates some examples of how one alert can have different investigation statuses and provide enough information to decide whether or not the investigation of that alert is still necessary. We will start with the initial status, when an alert is generated, and no one has yet any investigation details, and describe more complex scenarios where different parties provide information regarding the conclusions after their investigation.

Scenario	End-user Specific Workflow Indicator	MAH Specific Workflow Indicator	NMVO Specific Workflow Indicator	Alert Status
1	Blank	Blank	Blank	The Alert Status here could be seen as 'New', because none of the parties has started the investigation yet.
2	Root cause is on my side	No root cause on my side	Blank	In these situations, the Alert Status could be seen either as 'Under Investigation', in those cases where the NMVOs have the last word, but it can also be seen as 'Closed' in those situations where, following that particular country rules, the MAH or the End-user can close the alert investigation.
3	No root cause on my side	Root cause is on my side	Blank	This situation is similar to the scenario above, where at least one of the users has confirmed that the root cause was found.
4	No root cause on my side	No root cause on my side	Investigation Pending	This is one of those typical situations where the End-user and the MAH have started an investigation and concluded that no issue was found on their side. In these cases, one can deduce that the Alert




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Scenario	End-user Specific Workflow Indicator	MAH Specific Workflow Indicator	NMVO Specific Workflow Indicator	Alert Status
				Status is still ongoing, considering it, therefore, 'Under Investigations'. It might be that there was an issue with the National System which generated a false positive alert.
5	No root cause on my side	No root cause on my side	Root cause is on my side	This scenario could be the ending point of the previous one. After an investigation, the NMVO may have concluded that there was an issue with the NMVO and, therefore, can closed the case.
6	No root cause on my side	No root cause on my side	No root cause on my side	The Alert Status here could be seen as 'Escalated', because none of the parties has found any procedural or technical error and, therefore, the pack is considered potentially falsified. The alert shall be marked as 'Escalated' by the MAH or NMVO whoever is the last.
7	Root cause is on my side	Root cause is on my side	No root cause on my side	Another conflicting scenario could be this one, where both the MAH and the End-user believe that the root cause was on both sides. In this case, we are already on an edge case which deserves to be treated as such, and its final result may also depend on the country and the investigation details provided by each user.

This section should provide a view of how the individual indicators may support the different actors in taking a decision. The following section will explain in detail how the actors can also provide this information within the EAMS.

			
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5.2. Change the Alert Status

Upon receiving alerts, the end-users and MAHs will start their investigation and publish their individual status in the EAMS. Each party plays a different role, as specified in the sections before, namely in the previous section.

Following the previous section, once the investigation is done, the users may be able to provide a judgement of the global alert status, also known as "Alert status". For this reason, the EAMS also has this functionality available. As different countries may have different rules, there should be a manual action in line with the applicable rules in that country where the alert was generated.

The different Alert Status are:

New – As seen in the previous section, the 'New' status represents an alert when no action has been provided so far. This is the initial state of any alert. No user can set this alert status, it is automatically set by the system. The example which can be provided here can be seen below:

Scenario	End-user Specific Workflow Indicator	User	MAH Specific Workflow Indicator	User	NMVO Specific Workflow Indicator	User	Alert Status
1	Blank		Blank		Blank		New


Under Investigation – this status means that the alert is currently under investigation. The user may find technical issues with the EMVS, data upload, the person performing the verification or similar technical issues. MAHs, NMVOs, end-users and NCAs may set this alert state from another state according to the national rules. As soon as any user has modified an alert e.g., setting a status according to section User Specific Workflow Indicator, the status is automatically set from "new" to "under investigation". A possible scenario is the one below

Scenario	End-user Specific Workflow Indicator	User	MAH Specific Workflow Indicator	User	NMVO Specific Workflow Indicator	User	Alert Status
2	Root cause is on my side		No root cause on my side		Blank		Under Investigation

Closed – A closed alert means that the alert investigation has been carried out (on one or more packs), and it has been concluded that there was a technical or procedural root cause for the alert. Hence the pack is not a suspected falsified pack, and the alert can be closed. Please check the example below as a possible scenario:

Scenario	End-user Specific Workflow Indicator	User	MAH Specific Workflow Indicator	User	NMVO Specific Workflow Indicator	User	Alert Status
5	No root cause on my side		No root cause on my side		Root cause is on my side		Closed

Escalated – This status means that the investigation has been carried out, but the users (End-user or MAH) either identified a falsification or could not identify the root cause of that alert so that NCA

			
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intervention is required. MAHs, NMVOs, end-users and NCAs may set this alert state from another state according to the national rules. The example below shows a potential scenario where this alert User Specific Workflow Indicator could be set:

Scenario	End-user Specific Workflow Indicator	User	MAH Specific Workflow Indicator	User	NMVO Specific Workflow Indicator	User	Alert Status
6	No root cause on my side		No root cause on my side		No root cause on my side		Escalated.

Active – Active originally means that the root cause of an alert has not been found yet, but the alert is not being investigated actively by any user, therefore action is required. Please note that this state will be removed shortly, **so please, in the meantime, do not use this status.**


5.3. Predefined reasons

When setting the Alert Status, the EAMS requires users, MAHs, NMVOs and End-users, to select the reason for modifying the statuses. It is possible to use a reason from a predefined list (which can be seen below) or a custom one.

The table below shows the list of predefined reasons that can be used by the EAMS users when changing the alert status and the users/systems which can use the different reasons.

Table 2: Predefined reasons

User that can use the reason	Text
NAMS (NMVO)	No technical reason for alert identified by any party
NAMS (NMVO)	Time limit for the alert investigation exceeded
NAMS (NMVO/MAH)	Issue intended to be fixed by MAH (excluded for status "Closed")
NAMS (NMVO/MAH)	Issue fixed by MAH
NAMS (NMVO/MAH)	Issue cannot be fixed by MAH
NAMS (NMVO)	Local system error intended to be fixed by NMVO (excluded for status "Closed")
NAMS (NMVO)	Local system error has been fixed by NMVO
NAMS (NMVO)	Local system error cannot be fixed (NMVS issue)
NAMS (NMVO/MAH)	Not permitted request for pack state change by MAH for own product
NAMS (NMVO/end-user)	Issue intended to be fixed by end-user (excluded for status "Closed")
NAMS (NMVO/end-user)	Issue fixed by end-user
NAMS (NMVO/end-user)	Issue cannot be fixed by end-user
MAH	Issue intended to be fixed by MAH (excluded for status "Closed")
MAH	Issue fixed by MAH
MAH	Issue cannot be fixed by MAH


			
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User that can use the reason	Text
MAH	Not permitted request for pack state change by MAH for own product ²

The following examples will help the reader of this document to have a clearer idea of the idea behind these reasons:

Scenario	End-user User Specific Workflow Indicator	MAH User Specific Workflow Indicator	NMVO User Specific Workflow Indicator	Alert Status	Reason
1	Blank	Blank	Blank	New	N/A
2	Root cause is on my side	No root cause on my side	Blank	Closed*	End-user predefined reason: Issue fixed by end-user
3	No root cause on my side	Root cause is on my side	Blank	Closed*	MAH predefined reason: Issue fixed by MAH
4	No root cause on my side	No root cause on my side	Investigation Pending	Under Investigation	NMVO predefined reason: Local system error intended to be fixed by NMVO
5	No root cause on my side	No root cause on my side	Root cause is on my side	Closed*	NMVO predefined reason: Local system error has been fixed by NMVO
6	No root cause on my side	No root cause on my side	No root cause on my side	Escalated*	NMVO predefined reason: No technical reason for alert identified by any party
7	Root cause is on my side	Root cause is on my side	No root cause on my side	Escalated*	NMVO custom reason: Inconsistencies found between the end-user and the MAH's investigation results. Recommended

² This status can be applied when, for instance, an MAH publishes a pack status change twice, resulting therefore in alerts

			
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Scenario	End-user User Specific Workflow Indicator	MAH User Specific Workflow Indicator	NMVO User Specific Workflow Indicator	Alert Status	Reason
					escalation to the NCA.**

* Please note this is subject to that country's rule.

** Please note this is only an example and shall respect any country specific rules.

5.4. Predefined messages

The EAMS users can also change messages in case information is needed from anyone. For instance, the MAH may request the picture of the pack, or the end-user can interrogate the MAH regarding a specific subject, as well as the NMVO. For that purpose, the EAMS also allows the users to exchange messages. As with the predefined reasons, the users can opt either to choose custom messages, i.e. free text messages, or predefined messages.

The list of predefined messages can also be used by the different AMS users to facilitate the alert investigation.

Table 3: Predefined messages for alert investigation

User that can use the reason	Text
MAH	Recommended escalation to NMVO/NCA because MAH cannot find any errors
NAMS (NMVO/End-user)	Recommended escalation to NMVO/NCA because NMVO cannot find any errors
EMVO	Recommended escalation to NMVO/NCA because EMVO cannot find any errors


The predefined messages can be modified via the established change management process.

6. Transition period

A transition period might be needed until all countries start using an AMS. The EAMS is not a mandatory system, therefore countries not using a National AMSs (NAMSS) already by now may not use the EAMS subject to this handbook. There are also countries with a NAMS not connected to the AMS Hub. Therefore, MAHs may have to use other ways of communication to let NMVOs know about the result of the alert investigation. The Table 4 provides information regarding the way MAHs should manage alerts depending on the connection and use of an AMS.

To better understand the table below, please note that:

- **MAH** refers to the organisation that uploads product and pack data to the European Hub and therefore receives alerts for those products
- **Initiating market vs Fulfilling market.** The **Initiating market** refers to the market where the pack is physically located. This market may be the same as the one where the alert was raised during scanning.

			
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In the example where an alert occurs for a pack is in "PT", and the alert ID starts with "PT-", this difference is not impactful. However, in situations where intermarket transactions are required and alerts are raised, a pack in "PT" may actually cause an alert in "ES" NMVS when the authentication in "ES" NMVS cannot be achieved. This is the case when the master data is uploaded in ES but the physical pack ended up being distributed in PT for compassionate reasons for instance. Therefore, in this situation, **Initiating market** is "PT" and the **Fulfilling market** is "ES". These two countries have different roles. While the **Initiating market** is obliged to investigate the alert, the **Fulfilling market** can only support the investigation.

When the market in the alert is "EU", that means that the alert was generated in the EU Hub. In those cases, if EMVO is required to investigate the alert, a request shall be sent to the EMVO Helpdesk using helpdesk@emvo-medicines.eu.

Table 4: Scenarios how to act with regards to AMS connection

	MAH using the AMS connected to AMS Hub	Initiating market using the AMS	Fulfilling market using the AMS ³	Recommendation
Scenario 0	Yes	Yes	Yes	The EAMS shall be used for all communications regarding alert investigation.
Scenario 1	Yes	No	No	The MAHs can use the EAMS to update alerts. However, the information shall be extracted from the AMS to inform the relevant markets (please check section Appendix A – Country Specifications per action to see how MAHs can extract this information).
Scenario 2	Yes	Yes	No	The MAHs can use the EAMS to update alerts. If fulfilling markets are necessary to support the alert investigation then the communication shall be done using the pre-AMS ways of communication (emails, phone calls).
Scenario 3	Yes	No	Yes	The MAHs can use the EAMS to update alerts. However, the information shall be extracted from the AMS to inform the relevant markets (please check section Appendix A – Country Specifications per action to see how MAHs can extract this information).

³ only relevant for IMTs, i.e. when the Initiating market is different from the Fulfilling market.

			
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	MAH using the AMS connected to AMS Hub	Initiating market using the AMS	Fulfilling market using the AMS ³	Recommendation
Scenario 4	No	Yes	Yes	a. Communication shall be done using the pre-AMS ways of communication (emails, phone calls) b. MAHs can use the National AMS to update the national alerts in each market.
Scenario 5	No	Yes	No	a. Communication shall be done using the pre-EAMS ways of communication (emails, phone calls) b. MAHs can use the National AMS to update the national alerts in each market.
Scenario 6	No	No	Yes	The communication shall be done using the pre-EAMS ways of communication (emails, phone calls).
Scenario 7	No	No	No	The communication shall be done using the pre-EAMS ways of communication.

To be able to identify the countries using the EAMS, the users can obtain this information from the AMS Hub who knows which countries are already subscribed to the EAMS. This allows the connected MAHs to see whether or not a country is using the EAMS. For the MAHs using the AMS Portal developed by EMVO, the reader of this handbook can check out how to see this using the AMS Portal manual available in the OBP Portal (EMVO-01376 AMS User Manual).

7. Process flow legend

This document also provides the MAHs with a graphical way to visualise how actions can be taken for every kind of alert using the AMS. The following legend may improve the readability of the different diagrams. Please note that, below, where it is written "OBP", the reader can also read "MAH", taking into consideration that the OBP can represent the MAH namely when using the AMS Hub directly as the single point of connection to the EAMS.

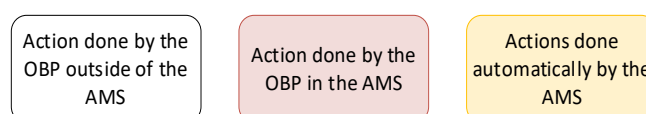



Figure 1: Process Flow Legend

			
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8. The MAH process and the EAMS

MAHs will be required to act differently depending on the alert type. This section provides a walkthrough on the different steps recommended to an MAH to ensure that all alerts are checked accordingly.

Please note that the actions described in this document are based on the document [EMVO-00306 Best Practice on Alert Handling](#), which describes in detail the business process. On the other hand, this handbook, is focused on the MAH interactions with the AMS Hub within the EAMS to fulfil the business process aforementioned.


Please note that country specific procedures can be found in the section [Appendix A – Country Specifications per action](#).

8.1. MAH-01 Part A - The MAH Determines alert type & source - A7, A24, and A68 Alerts and MAH-02 MAH documents alert, no further action required

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the “MAH-01. Determine alert type & source - A7, A24, and A68 Alerts” section of the best practices document. The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow

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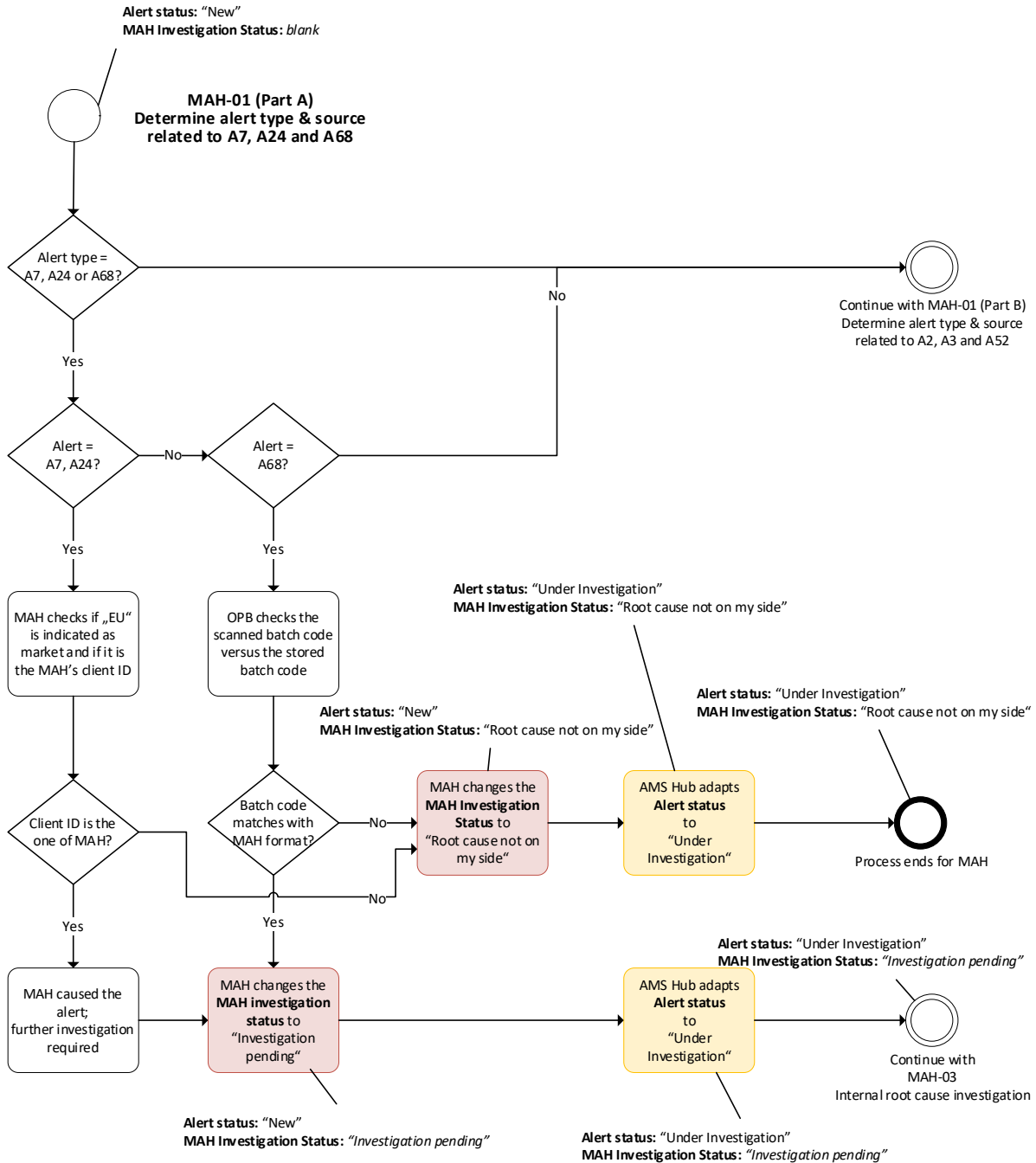



Figure 2: MAH-01 Process Flow


			
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8.2. MAH-01 Part B - The MAH Determines alert type & source – A2, A3, and A52 Alerts and MAH-02 MAH documents alert, no further action required

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section “MAH-01. Determine alert type & source - A2, A3 and A52 Alerts” of the best practices document.

Process flow

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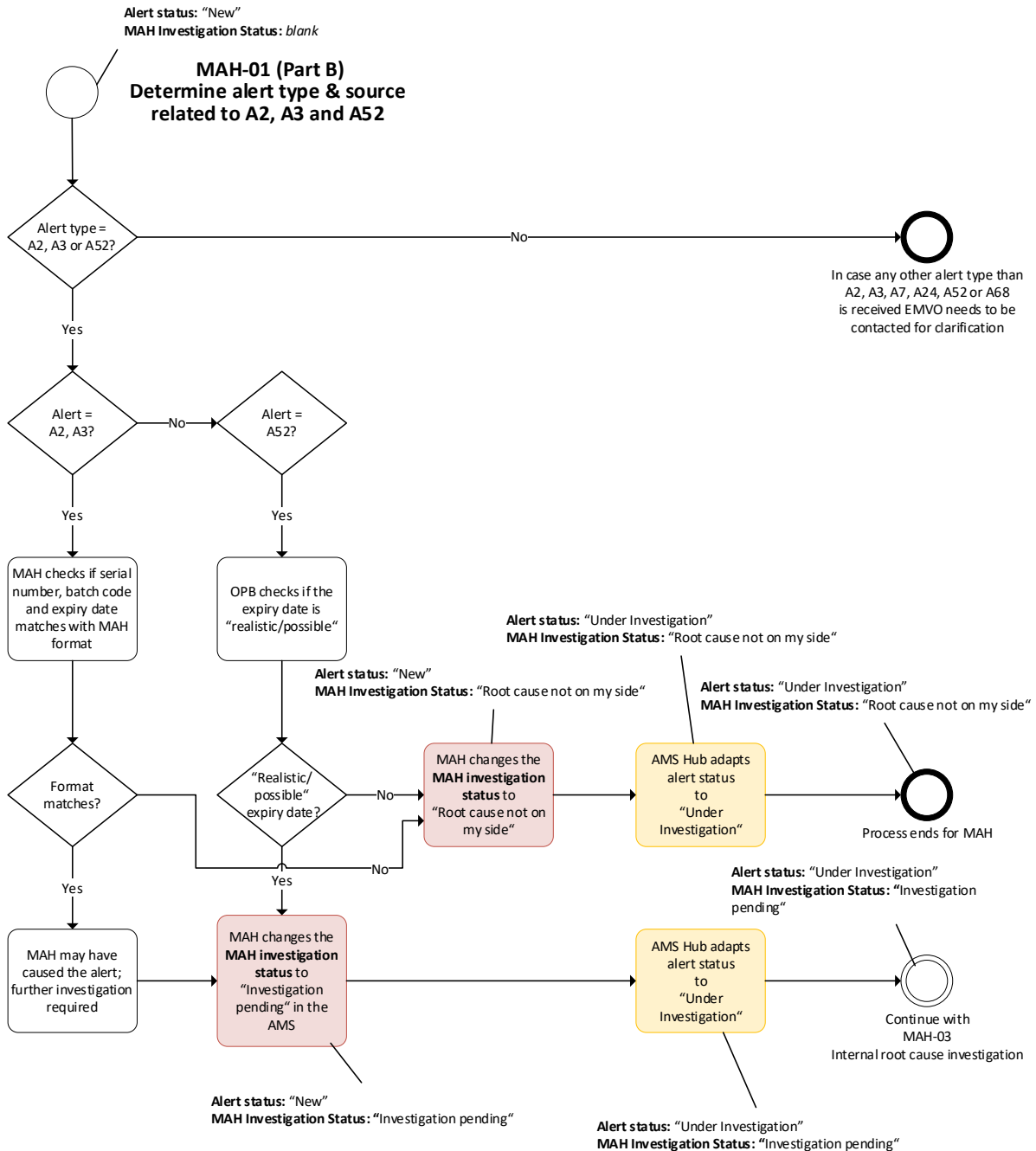



Figure 3: MAH-01 Part 2 - The MAH Determines alert type & source – A2, A3, and A52 Alerts and MAH-02 MAH documents alert, no further action required

			
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8.3. MAH-02 - MAH documents the alert, no further action

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-02. MAH documents alert, no further action required" of the best practices document. With the introduction of the EAMS, then there is no need to document this information, as it is expected to be done directly by the end-user or the NMVO.

The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow


N/A

8.4. MAH-03 - MAH internal root cause investigation and 03a The MAH takes/fixes the situation corrective action and informs NMVO

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-03. Internal root cause investigation" of the best practice document. The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow

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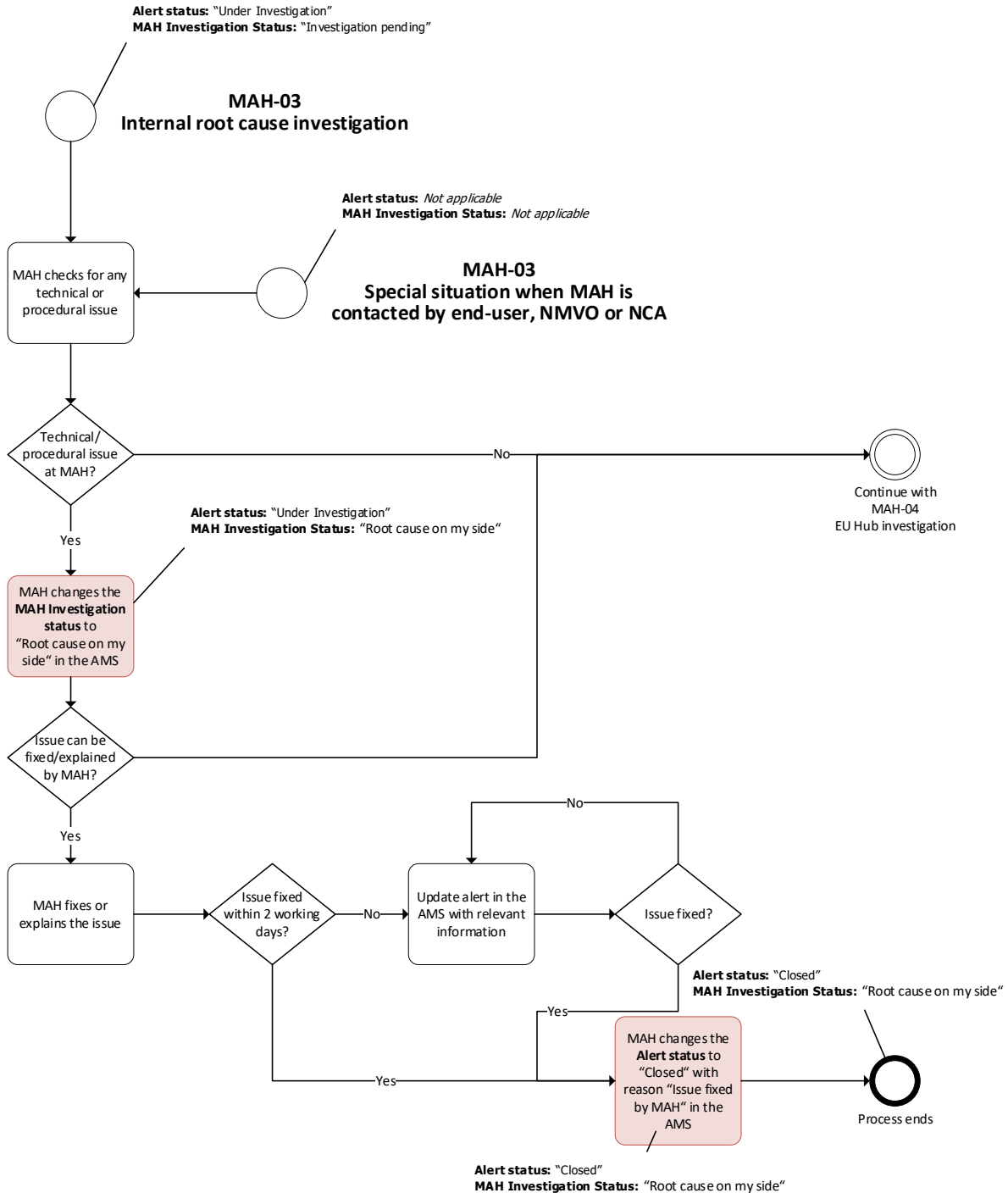



Figure 4: MAH-03 - MAH internal root cause investigation and 03a The MAH takes/fixes the situation corrective action and informs NMVO

			
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8.5. MAH-04 - EU Hub investigation

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-04. EU Hub investigation". The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow

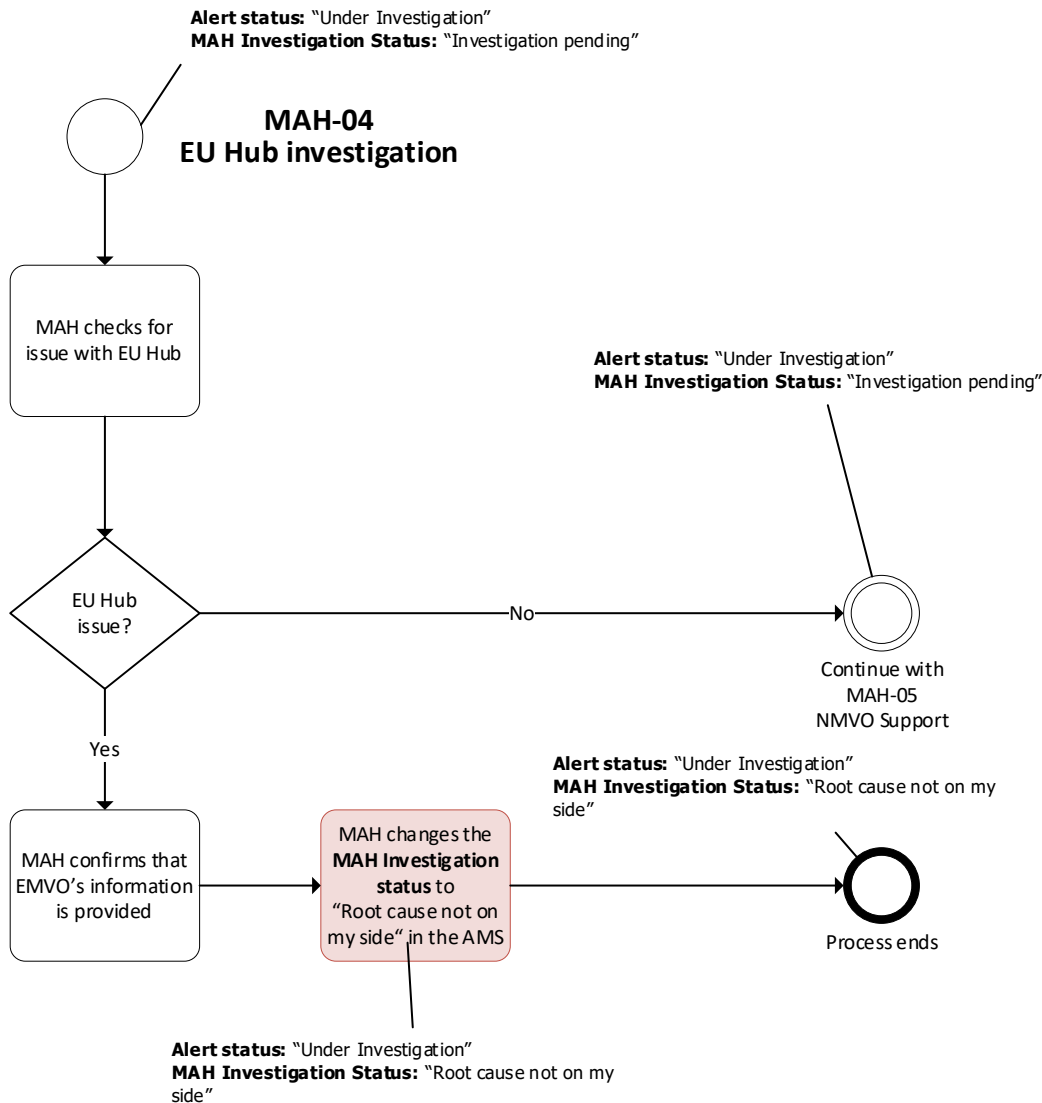



Figure 5: MAH-04- EU Hub investigation

			
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8.6. MAH-05 - MAH requests NMVO support

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-05. MAH requests NMVO support". The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow

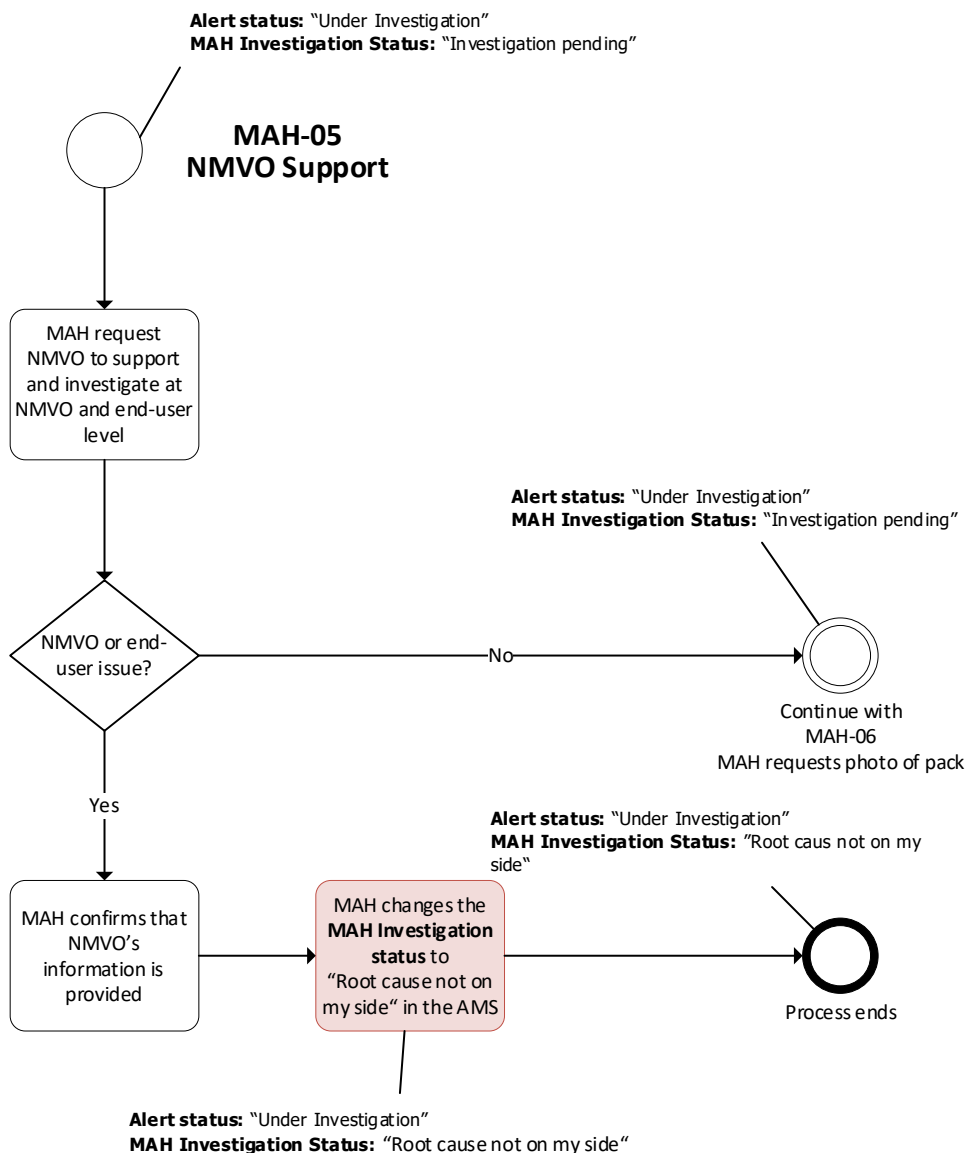



Figure 6: MAH-05- MAH requests NMVO support

			
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8.7. NMVO feedback

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-05a. NMVO feedback". The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow


There is no process flow for this action on the MAH side, as this action is done by the NMVO and the process flow part only relates to the MAH actions .

8.8. MAH-06 - Request Photo of Pack and MAH-06a confirms there is no indication of falsification and informs NMVO

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-06. MAH requests photo of Pack". The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

Process flow

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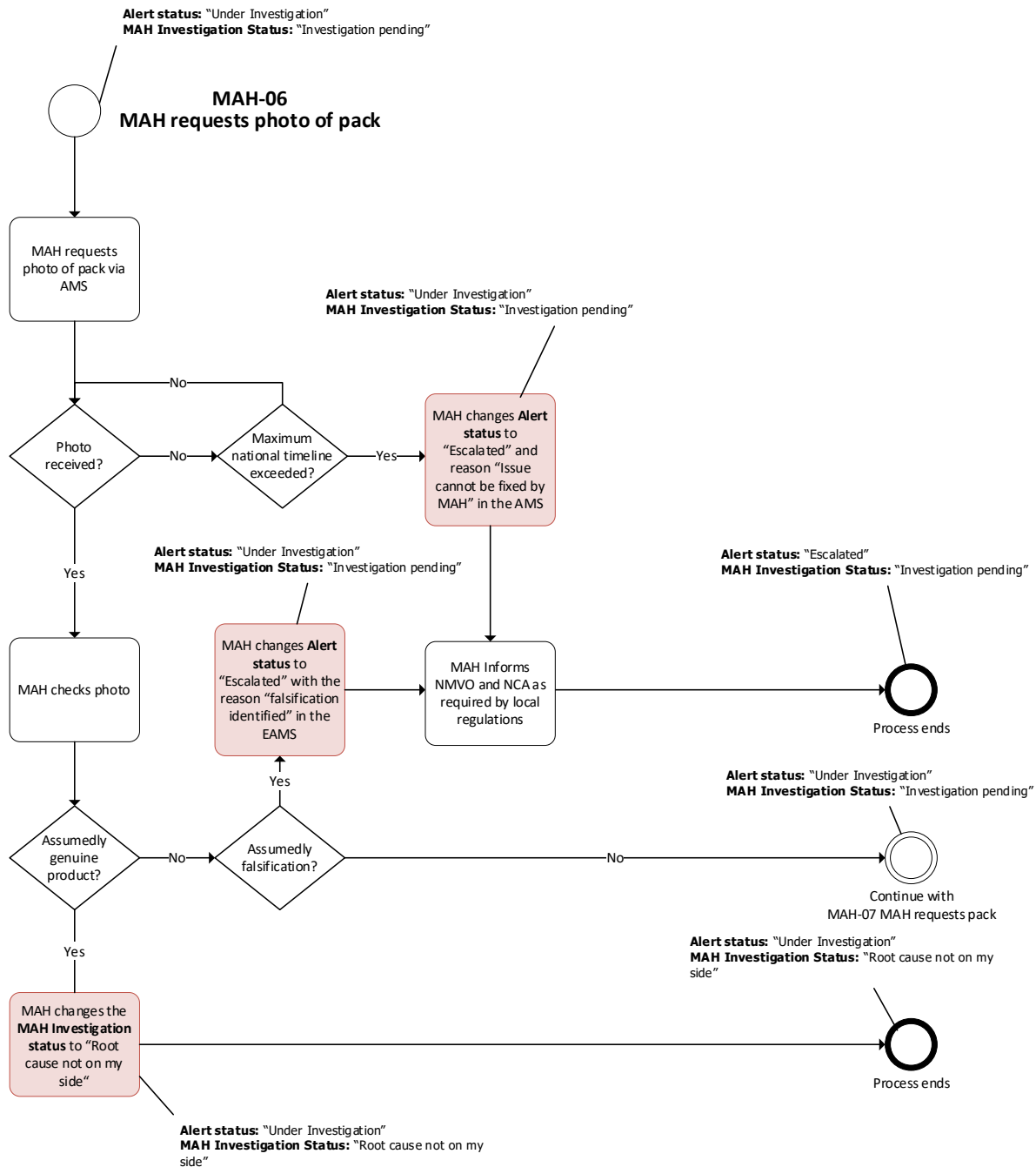



Figure 7: MAH-06 Request Photo of Pack and MAH-06a confirms there is no indication of falsification and informs NMVO

			
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8.9. MAH-07 - MAH Requests Pack and MAH-08 Suspected Falsification

The reference to the [EMVO-00306 Best Practice on Alert Handling](#) can be found in the section "MAH-07. MAH requests pack" and "MAH-08. Suspected Falsification". The country specific procedures can be found in the [Appendix A – Country Specifications per action](#).

- A pack is a suspected falsification if all possible technical or procedural root causes have been ruled out following investigation by MAH, end-user and NMVO;
- The MAH notifies NCA and EMA (for centrally authorised products) of suspected falsification according to applicable national or European legislation / regulations and the NMVO;
- Please note that national authorities shall be informed about a suspected falsification as soon as technical reasons for an alert can be ruled out. Investigation details can be exchanged to rule out any technical or procedural reason; however, before a pack is returned to the MAH for analysis, the NCA should be informed.

Process flow

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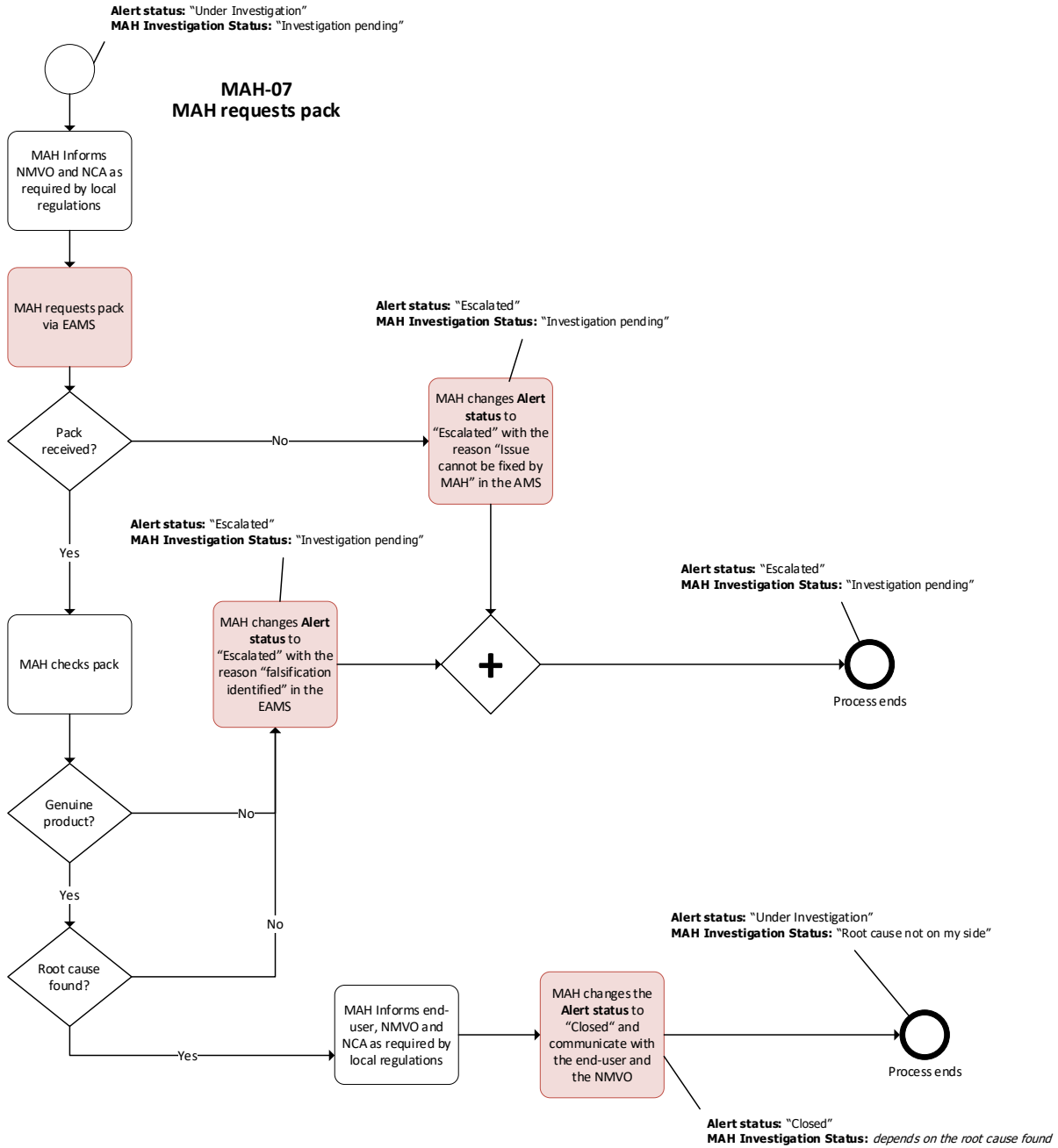


Figure 8: MAH-07. MAH Requests Pack and MAH-08 Suspected Falsification



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9 Reference document

Document ID	Document title
EMVO-00306	Best Practice on Alert Handling
EMVO-02048	Appendix A of EMVO-01392 EAMS Handbook for MAHs