

## **European Medicines Verification System**

### **IMT Investigation Process**

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IMT Investigation Process

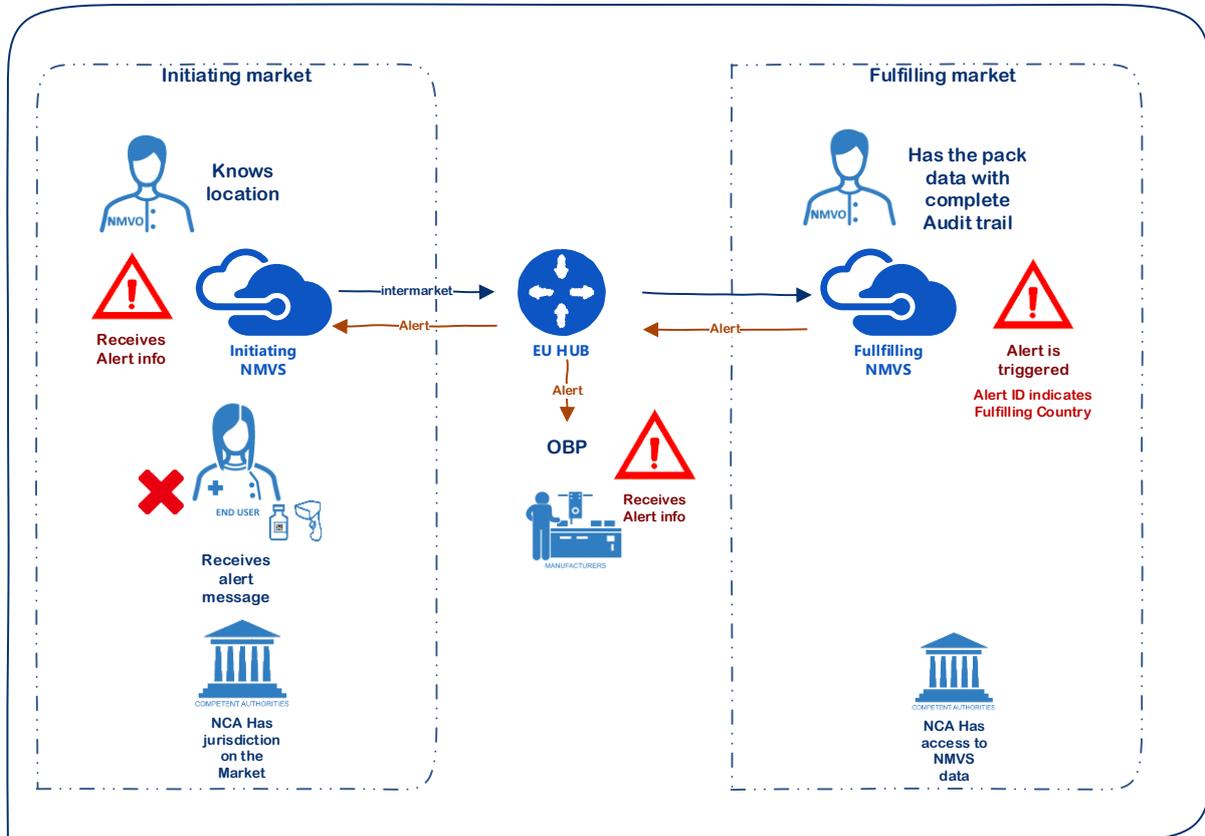
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## 1 Alert Investigation in case of IMTs



## 2 Actors and Roles

### 2.1 End User (e.g. pharmacy or wholesaler)

- Possesses the pack that initiated the Alert.,
- Is connected to NMVS in the initiating country,
- Was onboarded by and signed T&Cs with NMVO in the initiating country,
- Can only be inspected or sanctioned by NCA in the initiating country.

### 2.2 OBP / MAH

- Data owner for the product that caused Alert,
- Responsible for Alert investigation also in case where product owning MAH is not present in initiating country.

### 2.3 Initiating NMVO

- Is the authorised NMVO in the initiating country who onboarded the affected End User to the NMVS,

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- Has the legal responsibility to support End Users in the initiating market,
- Is cooperating with the NCA in the initiating country,
- Might not have a cooperation agreement with MAH,
- Does not have access to a full Audit trail

### 2.4 Fulfilling NMVO

- Is authorised for operating the NMVS in the country where the product data was uploaded,
- Has access to pack audit trail report
- Has a cooperation agreement with MAH

### 2.5 Initiating NCA

- Is authorised for supervision of all FMD stakeholders in the initiating market,

### 2.6 Fulfilling NCA

- Has access to Audit trail and other information in fulfilling NMVS

## 3 Recommendation

- All stakeholders in the initiating market have to follow national legislation and cooperate for assuring patient safety in the concerned country.
- Therefore it seems logical, that stakeholders in initiating country have to start investigation to determine root cause.
- OBP/MAH has to conduct an investigation, even when they are not an MAH in the initiating country.
- Many alerts can be resolved & root cause identified without accessing Pack Audit Trail Report.
- Fulfilling NMVO should provide support to Initiating NMVO if needed for purpose of:
  - Disclosing OBP/MAH contact information.
  - Providing the Audit trail details, or subset thereof, for those alerts (mostly A7, A24) where this information is needed for root cause determination.