Security elements – alarm handling

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18. JANUAR 2019

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Licensing and supervision

- Brexit
- Licensing of medicines
- Company authorisations and registrations
- Supervision and inspection
- Clinical trials
- Evaluation of reviews
- Report suspected illegal activities
- **Falsified medicines**
  - **Safety features - handling of alerts**
  - Pharmaceutical companies' reporting
  - Questions and answers
- Compassionate use

Safety features - handling of alerts

16 January 2019

Handling of alerts in the repositories system enters into force on 9 February 2019 under the safety feature provisions

The safety feature provisions enter into force on 9 February 2019 and aim to prevent falsified medicinal products from entering the legal pharmaceutical supply chain. The new safety requirements for the packaging of medicinal products and a new pan-European repositories system (medicinal products database) will make it possible to identify and verify the authenticity of the medicinal products comprised by the rules.

As part of the new safety requirements, the pharmaceutical manufacturer will be required to place safety features on the packaging of the respective medicinal products, namely a unique identifier in the form of a two-dimensional barcode as well as an anti-tampering device. The two-dimensional barcode must contain information on the product code, serial number, batch number and expiry date. A pan-European repositories system has also been established to which the pharmaceutical manufacturer must upload the information from the two-dimensional barcode before the product is released for sale or distribution. Finally, pharmacies and hospital pharmacies must verify the authenticity of the medicinal products by reading the two-dimensional barcode and retrieve the unique identifier and decommission the medicine in the repositories system while ensuring that the anti-tampering device is intact when the medicine is handed out to the patient.

Falsified medicines

- Duty to report identified falsified pack to NCA, whether being under suspicion or confirmed
- NCA examines the suspicious pack and delimits the scope
- Contact with the involved parties, hereunder companies and the authorities
- Initiate revoking of affected batches

When does suspicion of falsification arise?

- If a pack looks suspicious
- If the pack has been broken
- Past the 9th of February 2019:
  - When an alarm is triggered - and a technical- / procedural error can be excluded

Alarm – The role of the verying/deactivating unit

Pharmacy/Hospital pharmacy:

– The pack may not be handed out to patient

– Might the explanation to an alarm be a technical -/ procedural error on the location?

– The pack is to be placed in quarantine if the suspicion of falsification sustains

– Contact MAH/representative for MAH in order to clarify if the pack is under suspicion

Alarm – The role of the verying/deactivating unit

- Dialog with MAH/representative might cause following scenarios:
  - The suspicion is rejected.
  - The suspicion of falsification sustains.
  - Dialog with MAH/representative is not possible or slow.

- If suspicion of falsification sustains, the pack is to be returned to the respective wholesaler as soon as possible.

Alarm - The role of the verying/deactivating unit

Wholesaler:

– If the verifying unit, i.e. a wholesaler, discovers a status that will cause an alarm in the system, the wholesaler has to follow the procedure and take action on the warning.

Alarm – the role of the wholesaler

- The pack is received and placed in quarantine
- Might the explanation to an alarm be a technical -/ procedural error on the location?
- The wholesaler only has subjective verification.
- If suspicion of falsification sustains, the pack is to be returned to the manufacturer/MAH for testing of falsification

Alarm – The role of the manufacturer/MAH

– Report to NCA if a pack is under suspicion of falsification.

– A pack under suspicion is received by MAH and tested for falsification.

– The result of the testing is reported to NCA – Falsification is confirmed or rejected.
  - If a falsification is confirmed, reporting to NCA is to take place immediately.

Reporting to NCA

KP1

– The reporting schedules are under preparation:

- Name of the medicine, serial number, item number, batch number, pharmaceutical form, strength, expiry date.
- Where and when is the potential falsification detected?
- Reasons for suspicion of falsification?
- Can technical -/ procedural error on the location be excluded?

- To be send to: rapidalert@dkma.dk

Slide nummer 10

KP1 Katja Ploug; 23-01-2019

”Unknown” packs

– If a pack is produced prior to the 9th of February it might not be uploaded to DMVS. These packs can be detected over a 5 year period.

– NCA´s view is; no need to react on packs that are detected in the system as “unknown” within the 5 year period.

– Suppression of “unknown” packs depends on expiration date of the product.

– If a pack looks suspicious or has visible signs of falsification, reporting to NCA must take place.

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