Alert reporting via reklameraläkemedel.se

Instructions for using the form at reklameraläkemedel.se when reporting errors during e-verification

2nd of December 2019
Background

• A new form is being launched to report errors and alerts from pharmacies/wholesalers/retailers to the pharmaceutical company in question, to coincide with the introduction of e-verification of medicines

• The form is available at reklameraläkemedel.se from 8 February 2019 and in use from 9 February 2019

• The form is described on the following pages

• One report per pack is recommended
  – If relevant, several Alert IDs can be entered in a single report
News from 3rd of December 2019

• The update will:
  - provide for an easier way for reporting error messages and alerts
  - provide guidance that will improve the completeness in reports, which makes the handling easier and faster, both for the reporter and for the receiver
  - Give e-VIS possibilities to prioritise errands during investigation

• News:
  - The most common error codes that trigger reporting is now presented as options in a drop down menu.
  - Alert ID is to be reported in a separate field (If Alert ID is missing, this can be indicated in a check box)
  - Serial number is reported in a separate field (only if Alert ID is missing)
Description of reporting and reference to additional information at e-VIS’ website

New form 8 February 2019
How to complete the form – Step 1

1. Search for the product or input manually
2. Complete the obligatory fields
3. Click on ‘Next step’

Fields marked with * are mandatory
1. In the drop down menu, mark what kind of problem that will be reported
2. If relevant: Give a description of the error and if the alert has been reported to the Swedish MPA
3. If relevant, also state in the description field:
   - Patient cannot be dispensed with a different pack
   - Critical medication
   - The error was discovered upon delivery
   - Several packs appear to be affected by the error
4. Alert ID must be added, if Alert ID is missing, tick in the check-box “Alert ID saknas”
5. State whether the pack is in quarantine
6. Click on ‘Next step’
How to complete the form – Step 3

1. Enter contact details for the reporting location to which the pharmaceutical company can send notification regarding handling of the pack

2. Enter the coordinator and date the pack sent an alert

3. Click on ‘Report summary’
The form is sent to the same email addresses as the complaints reports from reklameraläkemedel.se

- Reporting pharmacy/wholesaler/retailers (email address stated on form)
- Pharmacy chain’s quality department*
- Pharmaceutical company
- Läkemedelsverket (Swedish Medical Products Agency)
- e-VIS
- Copy to LIF

*provided the pharmacy is identified using the form’s search function and that the pharmacy is part of a chain that has given an email address to LIF for complaints reporting
If the pharmaceutical company does not participate by providing contact details at reklameraläkemedel.se

• Handled in the same way as complaints, i.e. the form can be used to collect data and be printed out, but no report can be sent electronically to the company
• The user is informed of this in the form
Examples of emails

E-verifications and complaints reports from reklameraläkemedel.se have different subject lines and headings in the email.

If it is necessary to forward any of the report types to another email address, a rule can be added to the recipient’s email client.
Contact details

- Questions about the reporting form for e-verification: rodawebben@lif.se
- Other questions about e-verification: info@e-vis.se