# Guidance for completing the targeted veterinary recall notification form part 2, version 2025:1

**General**
*This form shall be used for the targeted recall of medicinal products for animals. The purpose is to not unnecessarily encumber pharmacies with information that does not concern them. Only information relevant to the current recall should be entered into the form.* ***The recall notification must be written in Swedish.***

*The following criteria should be fulfilled before considering targeting a recall:*

- Targeted recalls are used when the recall only concerns a small number of recipients (maximum of 15 pharmacies). Contact the wholesale distributor to receive this information and notify them that you are considering a targeted recall.
- The process depends on that only your identified recipient has received the goods and have full control over further distribution (e.g. to which health care providers).
- We propose that targeted recalls are only used when *one* wholesale distributor is involved, i.e. when you can identify the number of pharmacy recipients of the recalled product. We do not recommend targeting when sales have happened between wholesalers, when the total number of final recipients is unknown.
- In practice all recalls to wholesale distributor level follow the procedure of targeted recalls, but in this case use the normal recall notification.

The recall notification form consists of fillable fields and drop-down menus.

**Instructions (numbers are in reference to part 1, see "Vägledning till indragningsskrivelse del 1")**

1. Double-click to open the header and enter the recall date in the date field. The date specifies when the recall notification form is sent to the first-line wholesale distributor.

2. Click in the field and enter the company's recall identity number (for example year/serial number). The number is chosen by the company.

3. Please select the relevant RAS class and its description in the drop-down menu.

4. Complete the table. Add lines as required by clicking in the table and pressing the enter key or clicking on the plus-sign on the right. Add "(Licens)" after the name if the product is an unathorised medicinal product sold by license/named patient use and add both applicable item numbers (VARA group number and company internal number) in the "Varunr" field.

| Name | Dosage form | Strength | Pack size | Item No | RX/Ex [1] | EAN/GTIN | Batch No | Exp. Date |
|---|---|---|---|---|---|---|---|---|

[1]RX = prescription-only medicines, Ex = non-prescribed medicines

5. The cause for the recall should be described briefly. Adapt the language to the target group(s) e.g. pharmacy staff. If more extensive information is needed, a supplementary letter to a pharmacy/retailer can be sent together with the recall notice. A proposal for such a letter can be downloaded from the website of Röda webben.
http://lif.se/contentassets/1453080beb1044db955e6c60e6ed934a/indragning in a pharmacy letter of April 2015.docx

6. Please tick the appropriate squares for parties concerned by the recall. Hospital pharmacies should be indicated for recalls at the pharmacy level and health care providers should be indicated for recalls at the patient level and vice versa.

   - ☐ Distributor/wholesaler
   - ☐ Pharmacies or pharmacy service points
   - ☐ OTC retailers
   - ☐ Veterinarians
   - ☐ Animal owners

7. Enter the name of the first-line wholesale distributor.

If the recall concerns customers, read the document *Stöd vid indragningar som kan involvera konsument* to see which communication channels to use. Click in box E, click on  , switch to the text block for customer level recall and indicate in the textbox how information to users will be provided.

8. Enter the contact details of the company. Note that you should select a telephone number that can handle the load appropriate to the recall (e.g. telephone number to Medical Information Department).

9. Optionally insert the company's logo (not mandatory) by clicking the box and choosing an image.

10. This box is flexible, **i.e., it should be adapted to the current recall.**
    In the drop-down menus you can choose the relevant sets of measures to be taken by the recipients of the form. Click in each field, click  and choose a text block.

11. **Actions for Distributor/Wholesaler**
    The date of receipt of returns, should be related to the lead times for the other parties upstream the supply chain. The date should be established in dialogue with the wholesale distributor. Choose an appropriate date in the date field, normally around 2 months.

    **G. Actions Distributor/Wholesaler**
    - Stop all deliveries of the above medicinal product immediately.
    - Store recalled medicinal products separate from sellable stock.
    - Initiate recall from affected customers.
    - Provide for handling of returns and report to MAH by [date (e.g., within 2 months)]
    - Do not destroy or scrap returned recalled product until informed otherwise.

12. **Actions for Pharmacies/Pharmacy service point/Retail**
    If no recall is to be performed by pharmacies, choose "Ingen åtgärd" (no action) in the drop-down menu. Since pharmacies/retailers normally do not have batch traceability, the date of first delivery to Swedish pharmacies/retailers is important to facilitate the recall. Choose the appropriate date in the date field. If this information is not available, the line should be deleted.

13. Regarding dissemination of the recall notification and handling of returns, please choose the required actions in the drop-down menu. Return date is calculated from when the recall form is sent to first-line wholesale distributor. Choose an appropriate date in the date field, normally within 2-3 weeks.

    **H. Actions Pharmacy/Pharmacy service point/Retail**
    *First delivery to pharmacies/retailers in Sweden took place [date]*
    - Stop ordering recalled products.
    - Immediately remove recalled medicinal product from sellable stock.
    - Immediately remove recalled medicinal product which has been prepared or compounded for a patient.
    - Check that deliveries do not include recalled product over the next few days
    - Store recalled medicinal product separate from sellable stock.
    - Disseminate this recall notification so recall can be performed from veterinarians.
    - Disseminate this recall notification and perform recall from pharmacy service points' stock.
    - Return packs as soon as possible to the distributor or wholesaler who delivered the product. The return should be registered in connection with the physical return.
      [Or]
    - Recalled product should not be returned physically but should be destroyed in accordance with common procedures. Register a return with the distributor or wholesaler who delivered the product in connection with the destruction.
      The physical handling of the products should be performed [date within 2-3 weeks] at the latest. The return should be registered [date (2 months after recall date)] for crediting.

14. **Actions for Veterinarians**
    If no recall is to be performed by veterinarians, choose "Ingen åtgärd" (no action) in the drop-down menu. Return date is calculated from when the recall form is sent to first-line wholesale distributor. Choose an appropriate date in the date field, normally within one week.

**J. Actions Veterinarian (medicine lockers or similar at concerned health care providers)**

- Immediately remove recalled medicinal product.
- Immediately return recalled medicinal product to the supplying pharmacy. Medicinal product should be returned no later than [Date (within 1 week)].

15. Enter in the date field the date when the Swedish Medical Products Agency approved the recall notification form and check the associated box. This date may be earlier than the date the recall notification form is sent to the first line wholesale distributor.