

Guidance for completing the recall notification form part 2, version 2024:1

General

This form shall be used for the recall of medicinal products. Only information relevant to the current recall should be entered into the form. **The recall notification must be written in Swedish.**


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.


Name	Dosage form	Strength	Pack size	Item No	RX/Ex	EAN/GTIN	Batch No	Exp. Date
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¹RX = 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
 - Hospital pharmacies run by health care providers, including units performing automated dose dispensing and extempore production
 - OTC retailers
 - Health care providers
 - Consumer/Customer/Patient
7. Enter the name of the first-line wholesale distributor.
In cases where recall concerns a very limited number of recipients or concerns a very specific supply chain, the recall may be targeted. Use the template targeted recalls instead. This is available on Röda webben and the Swedish Medical Products Agency’s website.
If the recall concerns consumer/patient, read the document *Stöd vid indragningar som kan involvera konsument* in order to see which communication channels to use. Click in box E, click on , switch to the text block for patient level recall and indicate in the textbox how information to patients 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 manufactured 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 hospital pharmacies run by health care providers performing automated dose dispensing and extempore production
 - Disseminate this recall notification so recall can be performed from health care providers.
 - 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 hospital pharmacies run by health care providers, including units performing automated dose dispensing and extempore production**

If no recall is to be performed by hospital pharmacies, 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.

I. Actions for hospital pharmacies run by health care providers, including units performing automated dose dispensing and extempore production

- Stop ordering recalled products.
- Immediately remove recalled medicinal product from sellable stock.
- Immediately remove recalled medicinal product which has been prepared or manufactured for a patient.

- Check that deliveries do not include recalled product over the next few days
- Store recalled medicinal product separate from sellable stock.
- Immediately return any product in unopened packs to the pharmacy or distributor that delivered the product. Medicinal products should be returned no later than [Date within one week]. Medicinal product already in cartridge/tray should be destroyed in accordance with common procedures.
- Disseminate this recall notification so recall can be performed from end users at health care providers.
- Notify end users at health care providers to discard dose-packed product.
- Notify end users at health care providers to discard compounded product.

15. Actions for Health care providers

If no recall is to be performed by health care providers, 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 Health care provider (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)].

16. 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.