

Reporting of sales data for retail industry excluding pharmacies – instructions to the reporting person

Version 2.0

This document describes the two reporting services that may be used to fulfil the statutory obligation to submit data pertaining to the ex-pharmacy sales of certain over-the-counter pharmaceutical products.

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Introduction

You have disclosed to the Medical Products Agency that you are selling certain over-the-counter pharmaceutical products. Pursuant to the Medicinal Products Trading Act, the sales of certain over-the-counter pharmaceutical products must be reported to the Swedish eHealth Agency.

The reported sales data is used to generate comprehensive statistics of nationwide pharmaceutical sales. The statistics are then utilised by regions, government agencies, pharmaceutical companies, media and so forth. Sales data that can be attributed to any individual actor is classified as secret.

This document describes how you are to proceed with fulfilling the reporting obligation – and where to turn, if you should encounter any problems.

How to report sales of certain over-the-counter pharmaceutical products

Reporting is to be done through the eHealth Agency's website:

<https://www.ehalsomyndigheten.se/yrkesverksam/statistik-och-lakemedelsforsaljning/detaljhandel/>

There are two methods of reporting your sales – by online form and by file. Sales may only be reported using one of the methods.

If no sales have occurred during a month – despite the point of sale being registered with the Medical Products Agency – this must also be reported to the eHealth Agency. Such 'zero sales' cannot be reported by file, but only by web form. You can read more about this further in the user manual.

It is permissible to delegate another party to manage the reporting. This is known as engaging a reporting function. Such procedures are commonplace for stores that are a part of certain chains – where the chain usually acts as the reporting function. All actors have the possibility of engaging another party as the reporting function. However, the party who registers the point of sale is always responsible for ensuring that the reporting actually takes place.

Reporting requires a GLN code or Reporting ID. This code identifies the point of sale from which the sales data was generated.

If the point of sale itself does not submit a GLN code upon registration with the Medical Products Agency, the eHealth Agency will assign the point of sale with a Reporting ID that can be sent to the e-mail address provided at the time of registration. The Reporting ID can then be used in the same manner as a GLN code for reporting purposes.

You may report the sales on a monthly or quarterly basis – but sales data must be compiled (recognised) monthly. If you have sold any pharmaceuticals prior to obtaining your Reporting ID, the sale(s) must be compiled retroactively.

Reporting by file

<https://www.ehalsomyndigheten.se/yrkesverksam/statistik-och-lakemedelsforsaljning/detaljhandel/rapportera-via-fil/>

Reporting by file is best suited to actors who sell large volumes and many different articles. It is acceptable to create a file such as a Microsoft Excel file – but it is important to save the file in a text file format (tab separated) before uploading to the eHealth Agency's system.

When reporting by file, the result of the report's submission (acknowledgement) will be dispatched in the form of an e-mail confirmation. Therefore, it is important to provide a functioning e-mail address to the Medical Products Agency in conjunction with reporting the sales of over-the-counter medication – and to report any changes in your contact information.

If no over-the-counter medication was sold during the month, this cannot be reported by file. Use the webform for all such months and check the box, 'Nothing sold'.

A technical specification of the reporting file and sample are available at the webpage for reporting by file. It is important that the report file be formulated in accordance with the specification.

The submission of a report generates a confirmation e-mail that specifies whether the file was received in its entirety or in part, or if the file was rejected altogether. The e-mail will comprise a description of the error, if any. Consequently, it is important to read the confirmation e-mail carefully and for this reason, it is also important that the provided e-mail address is correct.

Reporting by online form

<https://www.ehalsomyndigheten.se/yrkesverksam/statistik-och-lakemedelsforsaljning/detaljhandel/detaljhandel-webbformular/>

Reporting by online form is suitable for small sales volumes or when no sales occurred during the month. If no over-the-counter medication was sold during the month, this is to be disclosed by checking the box, 'Nothing sold'.

When submitting a report through the online form, the result of the report (validation result) will take the form of an acknowledgement in the web browser.

Reporting function

It is acceptable to delegate another party to manage the reporting of data, but the party who registered (registrant) is always responsible for ensuring that reporting

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takes place.

The registrant of the point of sale is also responsible for informing the eHealth Agency if the point of sale is to be linked to a reporting function.

In the event that a reporting function is to be discontinued, the eHealth Agency must be informed, by either the reporting function or the point of sale concerned.

To register a reporting function, send an e-mail to registrator@chalsomyndigheten.se with information about the point of sale's corporate registration number and GLN code/Reporting ID, as well as the reporting function's corporate registration number and e-mail address. Please use the subject line: 'Trading in over-the-counter pharmaceuticals – Reporting function'.

Questions and answers about the reporting service

Must all pharmaceuticals be reported?

The Medical Products Agency makes decisions about which pharmaceutical products may be sold outside of pharmacies. Lists of these pharmaceutical products are available at the webpage:

<https://www.lakemedelsverket.se/en/trading-pharmaceuticals/retail-sale-of-otc-medicines/medicines-which-may-be-sold>

All of the pharmaceutical products on these lists are subject to reporting. They encompass both 'regular' over-the-counter medication and well-established plant-based pharmaceuticals (VBL).

However, traditional plant-based pharmaceutical products, natural medication and certain external remedies (VUM) are not normally included, but are, as a rule, sold without being subject to registration or reporting obligations.

When and how often should reports be submitted?

The party who conducts trading in pharmaceutical products is responsible for continuously reporting sales data to the eHealth Agency. The data forms a component of collected national pharmaceutical statistics and is used for purposes such as follow-ups and assessments within the pharmaceuticals domain. Pharmaceutical sales must be compiled every month and may be submitted on a monthly basis or quarterly basis.

A reminder is sent once per quarter if no report is submitted for a point of sale at any month during which the point of sale is registered with the Medical Products Agency.

The reminder is usually sent by e-mail, so it is important that the e-mail address is valid.

I received a reminder even though I submitted a report.

When submitting your report, an acknowledgement is issued, stating whether or not the report was approved – it is thus important to read this carefully. Remember that sales must be compiled for every month, even if reports are submitted on a quarterly basis.

If something else is wrong, contact the eHealth Agency by e-mail:

registrator@ehalsomyndigheten.se or call 0771-766 200 (local toll-free only).

I received a reminder, but I engaged a reporting function to manage my reporting.

You or your reporting function should contact us to ensure that your point of sale is linked to the correct centralised reporter. It would be ideal for you and your reporting function to collaborate on facilitating the reporting process.

I just reported sales statistics for the wrong month – what do I do?

The report cannot be deleted, but you can submit a new report for the same month, which will replace your previous report.

This means that you must submit a new report for all of the months that are impacted by your error.

My confirmation e-mail states that the ‘EAN code does not exist in the register at position 6’

You have reported a product whose EAN code/barcode is incorrect or does not exist in the Medical Products Agency’s list of over-the-counter pharmaceuticals that are permissible for sale at other points of sale than pharmacies.

I don’t know what I have reported during the quarter– what do I do?

Contact the eHealth Agency by sending an e-mail to:
registrator@ehalsomyndigheten.se or calling 0771-766 200 (local toll-free only).

My contact details have changed – how do I report this?

At the Medical Products Agency website – report changes in the operations: <https://www.lakemedelsverket.se/en/trading-pharmaceuticals/retail-sale-of-otc-medicines/selling-otc-medicines/notification-changes-and-denotification#hmainbody1>

The Medical Products Agency must be contacted regarding registration, deregistration, change of name or address for the company or store, or a change of e-mail address.

The eHealth Agency uses the contact information that is registered with the Medical Products Agency. It is important that the eHealth Agency has up-to-date contact information in order to maintain contact with the store, issue reminders and send information updates. The eHealth Agency is to be contacted if the change pertains to the reporting function who acts on behalf of other parties.

Must I submit my sales data to the eHealth Agency?

Those who sell certain over-the-counter pharmaceutical products are subject to reporting obligations under the law – reporting is not optional. The reports are used to generate overall nationwide statistics on pharmaceutical sales. The identity of the

point of sale is protected by statistical confidentiality, so that generated statistics cannot be used in any manner to show the sales performance of your particular store.

I want to stop selling pharmaceutical products – what do I do?

Remember to report your final sales. After doing so, deregister from the Medical Products Agency.

It is also important for the owner to deregister in the event of a change of ownership. If sales of over-the-counter pharmaceutical products are to continue, the new owner must personally register with the Medical Products Agency.

I have deregistered sales with the Medical Products Agency and sold my business. What do I do about the periods that have not been reported?

To fulfil your statutory obligations, you should, to the extent possible, report all sales that occurred prior to your deregistering your point of sale.

When I sell the store – can the new owner submit reports using my code?

No. The previous owner must deregister his/her operations via the Medical Products Agency and the new owner must register the new business, which will be regarded as a new store by the eHealth Agency.

What happens if I do not submit reports?

Reporting is prescribed by law. The municipality where the point of sale is located must verify compliance with this law. The Medical Products Agency is the supervisory authority and may issue injunctions or prohibitions to ensure compliance with the law. Such decisions may be combined with penalties.

We are pharmacy representatives – how do we submit reports?

Sales that are made by pharmacy representatives must be reported by the pharmacy and therefore, not through this channel. The point of sale, which is **both** a pharmacy representative and which also sells over-the-counter pharmaceutical products permissible under the Medicinal Products Trading Act must keep these operations separate. Only sales of the latter are to be reported.

Other questions

Please contact our support centre by e-mail to: registrator@ehalsomyndigheten.se, or call 0771-766 200 (local toll-free only).

Please be as detailed as possible when describing the issue, so that we can provide you with the best possible assistance. Indicate that it pertains to the reporting of sales outside of a pharmacy.