Important information about selling medicines
A number of regulations govern the sale of medicines

Medicines are not like any other product. If they are used or handled incorrectly, even non-prescription medicines can cause severe damage. As a result, those who sell medicines are subject to stringent requirements.

Sales of medicines are governed by the Act (2009:730), Ordinance (2009:929) and the Medical Products Agency's Provisions (LVFS 2009:20) relating to trading of certain non-prescription medicines. The purpose of the above-mentioned regulations is to ensure that medicines are handled and sold in such a manner that does not cause damage to humans, property or the environment, and that sustains the quality of the medicines.

The website for the Medical Products Agency provides regulations and information on trading of non-prescription medicines on the following page: www.lakemedelsverket.se/receptfrittbutik (in Swedish only).

NOTIFICATION
Before selling non-prescription medicines, you have to submit a notification to the Medical Products Agency. If you have several sales outlets, a notification must be submitted for each outlet. If any changes occur in your activities, e.g. a change in contact information, you must send notification of the change to the Medical Products Agency. The same applies if you want to stop selling medicines. The forms for notification and for changes/cancellation are available (in Swedish only) on the Medical Products Agency’s website.

SELF-REGULATION PROGRAMME
Before you start selling medicines, you have to compile a self-regulation programme. This programme shall comprise written instructions that clearly describe how medicines shall be handled and sold in your shop. The purpose of the programme is to provide support to your employees and ensure safe handling of medicines.

The Provisions laid down by the Medical Products Agency describe the instructions that, as a minimum, shall be included in the self-regulation programme.

PURCHASING
Medicines shall be purchased from a supplier that is an authorised wholesaler of medicines. It is not permitted for you to purchase medicines at a pharmacy or in any other shop and then resell them. Medicines shall have a Swedish label and be approved for sale in shops other than pharmacies. Please refer to the list on the Medical Products Agency’s website.
18-YEAR AGE LIMIT
Non-prescription medicines may only be sold to customers who are 18 years or older. Your shop must therefore implement routines for age control. Medicines containing nicotine may not be sold if you suspect that the medicine shall be handed over (peddled) to a person who is under the age of 18. Shops shall have a clearly visible and legible sign with information on the 18-year age limit. If you sell medicines containing nicotine, the shop shall also have a sign with information on the prohibition to sell such medicines if the salesperson suspects peddling of the medicines.

EXPOSURE AND STORAGE
Medicines must be stored either in a locked cupboard or under the direct supervision of personnel. The purpose of this is to prevent underage persons (under the age of 18) coming into contact with the medicines or that someone opens the package, removes or destroys the medicine or removes the package leaflet. Medicines must be stored separate from products that are not medicines. Customers shall be left in no doubt as to which products are medicines, and the best way to achieve this is with signs. Medicines must not be disposed of with normal waste or down the sink/toilet, but must be handled as special waste.

SUPERVISION AND FEES
The Medical Products Agency is the principal supervisory authority and charges a supervision fee that is currently SEK 1,600 per calendar year and per sales outlet. This fee is the same irrespective of the time of year notification (or cancellation) is made.

The municipality is responsible for monitoring sales of medicines and is entitled to charge a fee for monitoring. If the municipality detects severe or repeated deficiencies during monitoring, they will send a report to the Medical Products Agency, which is authorised to take further measures to ensure the retailer corrects the deficiency. The Medical Products Agency is also authorised to inspect shops that sell medicines.

SALES REPORTS
Sales reports are required specifying the amount of medicines sold in your shop. Reports shall be issued monthly/quarterly to the Swedish eHealth Agency (eHälsoomyndigheten) via their website: www.ehalsomyndigheten.se. Their website contains more information on reporting and contact information for the persons who can answer any questions you may have.

You are always welcome to contact the Medical Products Agency if you have any questions! Contact information for the Medical Products Agency:
+46 (0)18-17 46 00, email: registrator@mpa.se
This folder only addresses a few of the regulations that govern your activities as a seller of medicines. In order to ensure correct handling of medicines in your shop, it is important to read the regulations in full.

The website for the Medical Products Agency provides all the information available about selling non-prescription medicines on the following page www.lakemedelsverket.se/receptfrittikutik.

You will find the Act, the Ordinance and the Provisions and a guideline to the regulations (in Swedish only). The guidelines contain explanations and examples that may be of assistance for sellers of non-prescription medicines. The website also contains a template for a self-regulation programme and a list of non-prescription medicines that can be sold in shops other than pharmacies.