



Fimea Develops, Assesses and Informs

SERIAL PUBLICATION 1/2015

NATIONAL
OTC MEDICINES
PROGRAMME

fimea

NATIONAL OTC MEDICINES PROGRAMME

Serial Publication
Fimea Develops, Assesses and Informs 1/2015

© Finnish Medicines Agency Fimea 2015

Publisher

Finnish Medicines Agency Fimea
Postal address: P.O. Box 55, FI-00034 FIMEA
Telephone: +358 29 522 3341
www.fimea.fi

Distribution

www.fimea.fi/medicines/publications

ISBN 978-952-5624-51-9

ISSN-L 1799-7135

ISSN 1799-7135 (printed)

ISSN 1799-7143 (web)

CONTENTS

ABSTRACT	4	5.5	Challenges in safe OTC medication	19
1 INTRODUCTION	5	6	DISTRIBUTION NETWORK FOR OTC MEDICINES, MEDICINES INFORMATION AND ADVERTISING OF MEDICINES	20
1.1 Pharmaceutical policy background	5	6.1	Pharmacies as retail distributors of OTC medicines	20
1.2 Purpose and goals of the national OTC medicines programme	5	6.2	Pharmacy as a provider of counselling on OTC medicine use	21
1.3 Scope of the OTC medicines programme	6	6.3	Medicines information relating to OTC medicines and the advertising of OTC medicines	22
2 PREVALENCE AND SIGNIFICANCE OF OTC MEDICINE USE	7	6.3.1	Medicines information	23
3 CLASSIFICATION OF OTC MEDICINES	9	6.3.2	General principles of advertising OTC medicines	25
3.1 Legal basis	9	6.3.3	Monitoring of advertising	26
3.2 Regulatory processing of an OTC application for a medicinal product	10	7	EVALUATION AND DEVELOPMENT NEEDS OF APPROPRIATE OTC MEDICATION	27
3.2.1 National decision procedure	10	7.1	Therapeutic indications suitable for self-care	27
3.2.2 Centralised decision procedure in the EU	10	7.2	Measures for implementing safe OTC medicine	28
4 THE FINNISH OTC MEDICINE SELECTION	12	7.3	Finland's goals for the approval of OTC medicines under EU procedures	30
4.1 The Finnish OTC medicine selection in international comparison	12	8	CONCLUSIONS AND POLICY DIRECTIONS	31
4.2 Significant groups of OTC medicines and examples of current policies	12	SOURCES		34
4.3 Examples of medicinal products and therapeutic indications not approved for OTC care in Finland	14	APPENDICES		36
5 SAFE OTC MEDICATION	17			
5.1 Properties required of OTC medicines	17			
5.2 Adverse OTC drug reactions	18			
5.3 Pharmacovigilance	18			
5.4 Medication safety	18			

ABSTRACT

National OTC medicines programme. Finnish Medicines Agency Fimea. Serial Publication Fimea Develops, Assesses and Informs 1/2015. 47 p. ISBN 978-952-5624-51-9.

In 2012, Fimea was entrusted by the Ministry of Social Affairs and Health with the task of formulating a national OTC medicines programme. The programme delineates the objectives of and prerequisites for Finnish over-the-counter (OTC) medicines and discusses factors influencing the OTC medicine selection. Key stakeholder views have been sought in the preparatory stages.

The national OTC medicines programme lays down the related principles. The programme does not deal with the entirety of self-care, but focuses on the possibilities offered by medicinal products with a marketing authorisation as a component of self-care. The programme describes the factors guiding the OTC medicine selection and provides pharmaceutical industry stakeholders with assistance in understanding the marketing authorisation process. A survey of OTC medicine users in 2013 served as a backdrop for the programme.

In OTC medicine, some responsibility is transferred to the medicine user. In addition to a suitable OTC medicine selection, adequate advice and guidance are needed alongside the management of the user's overall medication, in support of successful therapy. The Finnish professional pharmacy system affords an excellent setting for providing counselling, but further work is needed on improving and harmonising such counselling. All stakeholders in the field play a role in providing medicines information, and counselling could be further improved by intensifying co-operation. Not enough research is available on the effects of OTC medicine on people's health behaviour, on the use of health services and on the possible reduction of the load on health care in Finland.

In terms of public health, the availability of OTC medicines in Finland is good in regard to time, location and selection. To ensure the effectiveness of health care, there may be a need to broaden the selection of OTC medicines in the market, but this must be effected in a controlled and safe manner. In this connection, it must be ensured that the products proposed for OTC care meet the criteria set for them within the programme. When a product is accepted as an OTC medicine, safety may in some cases be ensured by granting initially an OTC license only for a limited period, or by requiring that additional advice is given when dispensing the product. Harmonisation of the selection of OTC medicines within the EU is not an end in itself, but must take account of the variety of health care systems within the member countries.

As a follow-up to the OTC medicines programme, strong co-operation in developing the implementation of OTC medicine is expected from stakeholders in the Finnish pharmaceutical sector. Fimea can serve as a coordinator of such co-operation, but all stakeholders are expected to play both an active and proactive role.

1 INTRODUCTION

There has long been a need for a programme supporting national over-the-counter (OTC) medicine use and to outline the critical factors involved in self-medication. This need materialised as a goal when the Pharmaceutical Policy 2020 statement was formulated, during which various stakeholders mentioned the need for a separate OTC medicines programme. In 2012, the Ministry of Social Affairs and Health tasked Fimea with launching the preparation of such a programme. The programme has been prepared in co-operation with stakeholders in the pharmaceutical sector. No discrete national instrument or description of OTC medicine use had previously been developed.

1.1 Pharmaceutical policy background

The basis for the national OTC medicines programme lies in the policies laid out in the Pharmaceutical Policy 2020 statement (Ministry of Social Affairs and Health 2011a). According to this statement, safe OTC care forms part of health care in its entirety. On the other hand, inappropriate or incorrect use of medicines could undermine the results of pharmacotherapy, cause significant health hazards and increase the use of health services as well as the related costs. Comprehensive recording of medication data is an essential part of pharmacotherapy.

The aim of the Pharmaceutical Policy 2020 statement is to encourage medicine users to assume responsibility for their therapy. A key goal is to ensure good availability of medicines to the public, within a professionally operated dispensing system for medicines.

The guidelines for the national OTC medicines programme can be determined on the basis of the Pharmaceutical Policy 2020 statement:

- For example, self-care can be examined from the perspective of public health, industrial policy, medicine costs and freedom of choice for individuals. The starting-point of the OTC medicines programme is public health. For this reason, OTC medication is not examined solely from the viewpoint of the individual patient/consumer, but also from those of the public and health care at large.
- OTC medication will be developed to meet the needs of the customer, while being viewed as part of the entirety of (self-)care. The patient must be given greater responsibility in the care of chronic illnesses and minor ailments that can be easily self-treated. This means ensuring the availability of medicines suitable for OTC care, without unnecessarily replacing non-medical therapies with pharmacotherapy.
- A precondition for safe OTC medication is that medicine users have sufficient information on the disease to be treated, the treatment options available and the compatibility of the OTC medicine within their medication entirety.

1.2 Purpose and goals of the national OTC medicines programme

The purpose of the OTC medicines programme is

- to set forth the current state of OTC medicines in Finland (approval process illustrated with examples, selection of OTC medicines in international comparison, special features of the surveillance of OTC medicines)
- to evaluate the appropriateness of the current selection of OTC medicines in the market
- to describe the present criteria for approving a medicine as an OTC medicine, and to assess the possibilities of broadening the selection of OTC medicines in the market
- to identify development needs within the health services system, in order that the system will help ensure safe OTC medication.

The OTC medicines programme is seeking to describe the status of OTC medicines and the prerequisites for the evolution of the status. On this basis, another objective is the assumption of responsibility by the pharmaceutical sector in general for the further development of

safe OTC medication. Fimea can serve as one of the bodies coordinating further development.

The OTC medicines programme must adapt to the operating environment, such as the structural changes occurring in health care. It must therefore be subjected to periodic review and updating.

1.3 Scope of the OTC medicines programme

The OTC medicines programme does not concern self-care as a whole, but does consider other aspects of the subject. It does not concern veterinary medicines, traditional herbal medicinal products or homeopathic and anthroposophic products.

In addition, food supplements, cosmetic products and medical devices that are not medicinal products can be used in self-care and are accordingly excluded from the OTC medicines programme.

The OTC medicines programme is linked to the report on pharmacy services and other pharmaceutical services under way, and to the national medicines information strategy. It is possible that the report will further specify the activities of pharmacies, but under current legislation pharmaceutical personnel in pharmacies cannot make a diagnosis, prescribe treatment or systematically follow the course of a disease. The national Patient Data Repository information management service (Kanta) now in progress may improve the safety of OTC medication, if use of OTC medicines is registered as part of the patient's electronic medication list.

2 PREVALENCE AND SIGNIFICANCE OF OTC MEDICINE USE

Unlike other Nordic countries, in Finland the sale of OTC medicines is still limited to pharmacies, with the exception of nicotine replacement therapy and traditional herbal medicinal products. In 2013, in terms of wholesale, the largest groups of OTC medicines were nicotine replacement therapy (percentage of OTC medicinal product sales 18%), medicines for the gastrointestinal tract (16%), analgesics (15%), medicines for colds and coughs and other medicines for the respiratory system (14%), medicines for skin diseases (9%), medicines for the circulatory system (9%), vitamins and trace elements (7%) and antiallergics (4%). As a rule, OTC medicines are used for short-term, symptomatic treatment.

The wholesale price of an OTC medicine outside the reimbursement system can be freely determined by the marketing authorisation holder, but the margin received by pharmacies, and hence the retail price, are determined on the basis of the medicine tariffs decree. OTC medicines can be marketed directly to the public. With a few exceptions, they are not included in the Finnish medicine reimbursement system.

Sales of OTC medicines increased by almost 50% during the 2000s. Wholesale accounted for approximately 155 million euro in 2000, and for around 228 million euro in 2013. However, these sales figures give no indication of whether the number of users has increased or whether medicines have been used more frequently or in larger doses. According to a national survey conducted by Fimea in 2013, half of the respondents had used OTC medicines during the last week and one tenth uses them daily (Finnish Medicines Agency Fimea 2014a) (**Table 1**). In the mid-1990s, the percentage of daily users of OTC medicines was 7% of respondents (Sihvo et al. 2000a). There is no research data on the quantities used.

Table 1. Prevalence of use of OTC medicines in 2013 (n = 2 210). Source: Finnish Medicines Agency Fimea 2014a.

How often do you normally use OTC medicines?	Percentage
Daily	13
A few times a week	10
Once a week	8
1–2 times a month	27
Less often	34
Never	8

In 2001, as a percentage of the medicine costs borne by households, OTC medicines accounted for 37% (108/291 €), and in 2006 31% (117/373 €) (Aaltonen et al. 2013). In 2013, retail sales of OTC medicines (including nicotine products) totalled 75 euro per capita, compared to 50 euro in 2000.

Consumption of nicotine products more than tripled during the 2000s (in 2000: 2.9 DDD / 1 000 persons / day; in 2013: 10 DDD / 1 000 persons / day). In 2013, wholesale accounted for approximately 42 million euro, with pharmacy sales accounting for 7 million. Most of the increase in sales can be explained by the change in the distribution channel. According to studies of the health behaviour of the adult population, in the early 2000s around 10% of working-age people who had smoked during the past year had used a nicotine replacement product to support them in quitting smoking, whilst the corresponding percentage in 2010 was 16%. On the other hand, about 6% had used such products for reasons other than support in quitting smoking (Heloma et al. 2012).

Consumption of analgesics has also increased in the same period of time. For example, consumption of the most popular pain-killer, ibuprofen, has increased by nearly 50% (in 2000; total 15.5 DDD / 1 000 persons/day; in 2013: total 22.8 DDD / 1 000 persons/day). Paracetamol consumption has also increased considerably (in 2000; total 2.6 DDD / 1 000 persons/day; in 2013: total 5.4 DDD / 1 000 persons/day). The larger package sizes introduced to the market in the spring of 2008 partly explain the increase in ibuprofen consumption. In 2013, however, OTC consumption of ibuprofen began to decline for the first time.

On the basis of national survey, we know that OTC medicines are an important means of pain management (Turunen et al. 2004, Turunen et al. 2005). According to Turunen et al. (2005), half of respondents who had experienced pain during the last week had consumed OTC medicines. On the other hand, one in ten consumed OTC analgesics daily, which implies medicine use that is inappropriate. Problems related to the treatment of thrush have also been reported (Sihvo et al. 2000b). Almost half of the women who used thrush medicines used them contrary to the recommendations, while half reported symptoms that were probably due to other infections.

Sales of emergency contraceptives increased by 62% subsequent to their being transferred from prescription medicines to OTC medicines (Sihvo et al. 2003). This change in classification had no effect on the number of terminations. According to a survey of 12-18-year-old girls, neither did the change have any effect on the quantities of emergency contraceptives used by them (Falah-Hassani et al. 2007).

3 CLASSIFICATION OF OTC MEDICINES

During the period since Finland joined the EU, products have been classified as OTC medicines on the basis of EU legislation and the guidelines founded upon such legislation. EU regulations allow for national freedom of interpretation and, in respect of applications for non-centralised marketing authorisations, OTC decisions are always national. The selection of OTC medicines is influenced by various structures within the health care sector and the availability of services. Hence, the selection of OTC medicines varies markedly from country to country.

3.1 Legal basis

In assessing medicinal products, the same requirements for demonstrating efficacy and safety apply as for prescription products. Because both groups of medicinal products require a marketing authorisation, the same legal instruments and resolutions pertain to them. When a medicinal product is granted marketing authorisation, the national competent authority must determine whether the product a) requires a prescription or b) is a medicinal product that does not require a prescription prior to its release for consumption.

At EU legislative level, classification pertaining to the supply of medicinal products – into prescription and OTC medicines – is described in Articles 70, 71 and 72 of Directive 2001/83/EC of the European Parliament and of the Council (Directive on human medicines). These Articles determine when a prescription is absolutely required in order to obtain a medicinal product. The EU Commission has also issued guidance on applying the said Articles (A guideline on changing the classification for the supply of a medicinal product for human use).

Under Finnish national legislation, the classification of medicines for supply is prescribed in Section 9, paragraph 1 of the Medicines Decree (693/1987), according to which, when granting a marketing authorisation, the Finnish Medicines Agency Fimea must decide whether the product can be sold or otherwise released for consumption on the basis of a prescription only. Pursuant to Section 9, paragraph 2 of the Medicines Decree (693/1987), Fimea may change the decision referred to in paragraph 1 on the basis of new information obtained on the medicinal product which has a bearing on the classification for supply.

Pursuant to Section 2 of the Act on the Finnish Medicines Agency (593/2009), the Agency has the task of "taking care of the pre-marketing and post-marketing surveillance of medicines" and "controlling and monitoring the manufacture, import, distribution, advertising and release for consumption, of medicines".

In accordance with Fimea guideline 2/2013 on obtaining and maintaining a marketing authorisation and registration, the applicable provisions of the Directive on human medicines are taken into consideration when determining the terms and conditions governing the supply classification of a medicinal product".

On the basis of the above norms, the classification of a medicinal product as an OTC product or a prescription product is determined by Fimea. Fimea may determine on such a classification during either the pre-marketing or post-marketing surveillance of the medicinal product. If the marketing authorisation holder wishes to change the classification of the medicinal product from a prescription product to an OTC product, the holder must present Fimea with the medical grounds for such a change, by application. The burden of proof for approval of a change in classification lies with the marketing authorisation holder.

On a national basis, Fimea makes OTC decisions on marketing authorisations, based on the national, decentralised and mutual recognition procedure. Under the centralised procedure for marketing authorisation, decisions are made by the European Commission.

Key legislative norms and regulations:

- Directive on human medicines 2001/83/EC
- Medicines Decree 693/1987
- Fimea regulation 2/2013: Applying for and maintaining a marketing authorisation for a medicinal product
- Notice to Applicants, part2C – A guideline on changing the classification for the supply of a medicinal product for humans.

3.2 Regulatory processing of an OTC application for a medicinal product

3.2.1 National decision procedure

Fimea assesses the suitability of medicinal products that have been granted a national marketing authorisation for OTC care. Approval of a medicine for OTC care is an important decision, which is taken into account in the assessment process. The applicant or marketing authorisation holder initiates the OTC procedure as an application for a variation to the marketing authorisation, or when applying for a marketing authorisation.

Scientific experts in the relevant therapeutic field carry out a preliminary assessment of the OTC application. If the OTC application relates to a medicinal product for which a corresponding product (the same active substance at the same strength and in the same or a smaller package size) is already an OTC product, the product information necessary for self-care is assessed. This must be in compliance with the product information already accepted.

If the OTC application relates to a new therapeutic indication, a new active substance, greater strength, a new method of administration, a new target group or a larger package size relative to the OTC decisions already made, the main elements of the criteria for OTC care laid out in the European Union's marketing authorisation guidelines are checked on the basis of the documentation appended to the OTC application, during which an assessment is performed of whether the criteria for OTC care have been met. In assessing OTC applications of significance to public health or the present health care system, use is made of opinions requested from stakeholders when necessary.

In addition, other information brought forward by the applicant, such as OTC decisions taken in other EU member states, is taken into account when assessing the OTC application. However, all submitted OTC applications are reviewed from the viewpoint of the Finnish health care system. After an assessment has been drawn up, the application is processed by the management group for the assessment of medicinal products, to ensure that the proposal is in line with the practices that have arisen from earlier decisions. The decision on the OTC application is made by the director of the assessment process, based on a presentation by the Senior Medical Officer.

An affirmative OTC decision presupposes that the patient has sufficient information. In this, the package leaflet and labelling play a key role.

An applicant can appeal to an administrative court against a negative decision taken by Fimea, after which the court will take a final decision on the matter.

3.2.2 Centralised decision procedure in the EU

Decree 726/2004 of the European Parliament and of the Council defines the medicinal products that must be approved under the European Union's centralised marketing authorisation procedure. Other products meeting the conditions laid down in the Decree can be approved under the same procedure. Pursuant to the Decree, in addition to innovative medicines, medicines that do not involve an innovation but which may be useful to the public or to patients if they are immediately granted a Union-wide marketing authorisation, can be approved via the centralised procedure. These include certain medicines that can be released for consumption without prescription, such as medicines for use during an influenza pandemic.

Several marketing authorisation applications for medicinal products intended for OTC care have been processed using the centralised procedure. Medicinal products containing orlistat, pantoprazole, esomeprazole and ulipristal have so far been approved as OTC medi-

cines. In the cases of the OTC applications for sumatriptan and sildenafil, the result was either a negative decision or the withdrawal of the application. Consideration of OTC applications has often ended in a vote, from which it can be inferred that the European Medicines Agency's (EMA's) policy on OTC medicine is still taking shape. As its guiding principle, the centralised procedure holds that an approved product should be subject to fully equivalent conditions for release for consumption in all member countries; in other words, the medicinal product can be freely released for consumption between member countries. Hence, it is clear that a decision made via the centralised procedure brings OTC medicine practices in the member countries into alignment, not only with respect to the product concerned but also for similar products and even products in the same category. For this reason, the EMA's approval procedure for OTC medicines has a significant impact throughout the European Union.

4 THE FINNISH OTC MEDICINE SELECTION

The Finnish OTC medicine selection has developed over the years and reflects the understanding of pharmacotherapy current at any given time. The current, relatively broad selection of OTC medicines is the result of decisions made by the regulatory authorities, since the time of the National Board of Health and the National Agency for Medicines.

4.1 The Finnish OTC medicine selection in international comparison

In evaluating the use of OTC medicinal products, Sweden, Norway and Denmark are still most readily comparable with Finland, despite the most recent changes made to the distribution channel. Such comparability is due to the similarities between these countries in terms of their society, standard of living, health care and surveillance of medicines. Prior to Finland's and Sweden's EU membership, the Nordic countries engaged in significant co-operation in surveillance of medicines. This contributed to the formation of uniform fundamental principles in surveillance, the selection of medicinal products and the selection of OTC medicines. At present, official Nordic co-operation largely takes place within the context of EU co-operation.

According to the Association of the European Self-Medication Industry AESGP, Finnish OTC medicine includes more active substances than in the other Nordic countries. In Finland, there are 78 active substances, whereas there are 72 in Denmark, 70 in Sweden and 60 in Norway.

According to the AESGP statistics, the OTC medicine market in Finland is clearly larger in terms of sales value than those of Norway and Denmark and corresponds to 65% of the Swedish market. In Finland, sales of OTC medicines are the highest per capita among the Nordic countries. However, no direct conclusions can be drawn from these statistics on the consumed doses of OTC medicines.

In Britain, Germany, Portugal and Belgium, the numbers of active substances included in OTC care are the highest in Europe. The smallest numbers are recorded in Croatia, Greece, Bulgaria and Slovenia. As such, the number of different active substances included in OTC care does not necessarily entail a varied selection in terms of the therapies available, since a selection including just a few different substances and pharmaceutical forms is usually sufficient to cover the individual needs of any single therapeutic indication.

4.2 Significant groups of OTC medicines and examples of current policies

In the following, the most significant and largest OTC medicine groups and the related regulatory policies will be described. A complete list of approved OTC products is available on the Fimea website. Information for international comparison has been obtained from the statistical data on the AESGP website (www.aesgp.eu). Although this information is not official, it can be used to illustrate the case in question.

Nicotine products

Nicotine products are intended for withdrawal treatment in connection with smoking cessation. Since these products can be obtained over-the-counter, they can be widely used for quitting smoking. In addition to pharmacies, nicotine products can be sold by all shops that are licensed to sell tobacco products. All pharmaceutical forms of nicotine products with a marketing authorisation are available for OTC use. The change in the distribution channel has increased the consumption of nicotine replacement products. There are also indications that the change in the distribution channel has brought about a change in the intended use of nicotine products (cf. Chapter 2). The selection of nicotine products in Finland is similar to that of the other Nordic countries.

Analgesics

Analgesics in OTC use are intended for the care of temporary pain and fevers. In Finland, ibuprofen, ketoprofen, paracetamol and acetylsalicylic acid in oral form are available over-the-counter. Ibuprofen, paracetamol and acetylsalicylic acid are also available as combination products with caffeine and/or ascorbic acid.

Anti-inflammatory medicines such as diclofenac and piroxicam are available as topically administered OTC products in Finland.

In Sweden, oral diclofenac and naproxen products are also available, but ketoprofen products are not available over-the-counter. Naproxen products can be purchased from grocery stores in Sweden. In Denmark, products containing diclofenac, ketoprofen and naproxen are prescription medicines. In Finland, OTC paracetamol products include tablets containing up to 1 g of paracetamol. In Sweden, Norway and Denmark, the maximum tablet strength is 500 mg.

The evaluation of medicines for approval as part of the selection of anti-inflammatory OTC medicines emphasises the suitability of the product for short-term use and for rapid pain relief, while taking account of its safety profile. For this reason, some anti-inflammatory medicines, such as diclofenac and naproxen, are not in OTC use. The present use of old OTC medicines, such as acetylsalicylic acid and paracetamol, does not fully correspond to the criteria currently employed in the evaluation of OTC medicines. However, the authorities have limited possibilities to intervene in the conditions of use of medicines already approved. To remove these products from the OTC selection, we would need to be able to establish the presence of a sufficiently serious public health hazard. Furthermore, as a rule national removal from OTC care would also launch an EU-wide inquiry process in respect to such products.

Gastrointestinal medicines

Of the medicinal groups intended for the OTC care of gastrointestinal symptoms, the most frequently used include laxatives and medicines for treating heartburn.

With the exception of prucalopride succinate, all medicinal products for constipation containing laxative substances are available over-the-counter. Furthermore, in some products a larger package size, reimbursed at the basic reimbursement rate, is available on prescription. Sales of OTC constipation medicines are slowly increasing, by around two per cent a year. This is probably due to the ageing of the population. Between the Nordic countries, the selection of OTC constipation medicines is very similar.

The proton pump inhibitors lansoprazole, omeprazole, esomeprazole and pantoprazole, the H₂-receptor antagonists famotidine and ranitidine, antacides, i.e. conventional aluminium-calcium-magnesium compounds, and alginic acid, sucralfate and magnesium hydroxide are available over the counter for the care of heartburn.

The OTC medicine selection for heartburn has grown from antacides and sucralfate to include H₂-receptor antagonists and proton pump inhibitors. Proton pump inhibitors were included in the OTC regime through the European Union's centralised procedure in 2010. Fimea's previous negative stand on the OTC classification of proton pump inhibitors was based on concern about the delayed diagnosis of serious diseases.

Cough medicines

The cough medicines available include the mucus-thinning compounds bromhexine and the related combination products carbocysteine, acetylcysteine, guaifenesin and cocillana extract, and the cough-suppressants dextromethorphan, clobutinol, pentoxyverine and codein. In Finland, the OTC selection of cough medicine products is probably the broadest among the Nordic countries and, according to AESGP statistics, OTC consumption is the highest.

The use of cough medicines in self-care represents an old tradition in pharmacotherapy. Today, health care professionals widely share the opinion that the cough medicines used as OTC medicines are ineffective. However, it is difficult for the medicine regulatory authority to change the classification of medicines that have attained OTC status, without obtaining concrete evidence of the hazards involved. On the other hand, little reliable data is available on the hazards involved with OTC medicines, and consumers lack the opportunity to follow the scientific discussion on the efficacy of cough medicines.

Antiallergics

Of antihistamine tablets, OTC products containing cetirizine, levocetirizine, loratadine, desloratadine, ebastine, fexofenadine and acrivastine are available. In 2008, the size of the largest OTC pack of antihistamine tablets increased from a 10-day course to a 30-day course of therapy. At the same time, OTC sales of antihistamine tablets increased by several dozen per cent.

Antihistamines containing azelastine and levocabastine in nasal spray form and disodium chromoglycate are available for the self-care of allergy. In addition to these, ketotifen and lodoxamide are available as eye drops. Furthermore, the selection of OTC medicines for the treatment of allergic nasal symptoms includes glucocorticoid nasal sprays containing beclometasone, fluticasone, mometasone and triamcinolone.

The Finnish OTC antiallergic selection is fairly comprehensive compared to the other Nordic countries. Long-term OTC use of antiallergics is considered possible, because the course of the disease can be weighed up by the patient and does not require continuous medical supervision.

Systemic fungicides as a supplement to topical treatment

Finland was the first Nordic country in which a 150 mg fluconazole capsule pack became available for the OTC single-dose treatment of recurring vaginal thrush which has been earlier diagnosed by a physician. This oral product complements and broadens the OTC care options, such as topical products, intended for vaginal thrush infections. In Sweden, a corresponding decision was made in the autumn of 2013.

As a rule, oral antimicrobial medicines have not been approved for OTC care. This is due to concerns about the needless use of such preparations and the possible development of medicine resistance. However, in the case of yeast infections, since the danger of medicine resistance was considered minor, improving the availability of the medicine for the patient and health care was deemed appropriate.

4.3 Examples of medicinal products and therapeutic indications not approved for OTC care in Finland

Simvastatin

OTC status for simvastatin in small doses has been sought for very broad therapeutic indications covering the majority of the population. Simvastatin's suitability for OTC care was charted during an extensive consultation round that included a wide range of medicine users, prescribers and distributors.

Most of the submitting parties were of the opinion that the proposed small dose would result in less effective care of patients who really needed the medicine and to unnecessary use in low-risk patients. Further, the respondents voiced the concern that monitoring of the treatment and non-medical treatment would suffer with the reduction in regular follow-up.

In the case of chronic diseases that require monitoring and comprehensive care, OTC status must also be weighed up from the viewpoint of self-care, medical follow-up and guidance supporting non-medical treatment.

Glucosamine

Glucosamine is a well-tolerated product that has been proposed for inclusion in the OTC regimen for the treatment of osteoarthritis. In principle, this product would provide an alternative to anti-inflammatory medicines.

However, studies indicate that glucosamine begins to take effect slowly, over the course of several weeks. Studies conducted and research overviews published in the last few years have questioned the efficacy of glucosamine. One of the results of this new understanding is that glucosamine is no longer recommended for the care of osteoarthritis. It is difficult for consumers to obtain information on such reappraisals of the efficacy of medicines. Nor is it possible for a patient to determine the reason for joint pain and the required therapy on his or her own. Osteoarthritis requires a diversified non-medical treatment, which also consti-

tutes the primary therapeutic approach to this disease. Furthermore, an extensive consultation round has been used to gather views on the use of glucosamine in OTC care.

As a result, glucosamine marketed as a medicinal product for the care of diseases has remained under prescription. On the other hand, glucosamine can be obtained as a nutritional supplement which does not involve the treatment of a disease.

Sumatriptan

Sumatriptan or other triptans intended for the care of migraines have not been approved for OTC care in Finland, although sumatriptan is available as an OTC product in Sweden, for example. In Finland, triptans are not viewed as meeting the criteria for OTC care. In 2011, the EMA reached the same conclusion.

Diagnosis of a migraine requiring triptan therapy and distinguishing it from headaches requiring other kinds of therapy is not necessarily possible through self-care. Triptans are not considered as safe as the analgesics approved for OTC care, which can also be used to treat headaches. Triptans can also involve significant cardiovascular hazards and interactions with commonly used medicines (cf. **Appendix 2**).

Pharmacotherapy of psoriasis

OTC status has been sought for a topical product for psoriasis treatment enabling short-term, self-care treatment. Since psoriasis is a chronic skin disease, its overall care should be conducted together with a physician, particularly since psoriasis can be associated with the exacerbation of another systemic disease (Type 2 diabetes, for example).

Pharmacotherapy of hypertension

Hypertension is a chronic disease that can last a lifetime. The diagnosis and differential diagnosis of hypertension should be performed by a physician. Hypertension is initially treated with non-medical treatment. If pharmacotherapy is deemed necessary, the medicine must be selected individually for each patient with regard to the overall situation. Therapy is often performed based on one or more active substances. Pharmacotherapy can be intensified or attenuated when necessary, or can be discontinued altogether. Hypertension can be associated with other common public health problems, such as Type 2 diabetes, coronary heart disease or cardiac dysfunction. Hence, the pharmacotherapy of hypertension should not form part of OTC care.

Pharmacotherapy of diabetes

Type 2 diabetes is a chronic, progressive disease usually lasting a lifetime, the early diagnosis of which has been emphasised over the last few years.

Prevention of diabetes through changes in lifestyle – increased exercise and moderate weight loss – has had convincing results among high-risk groups. Pharmacotherapy has no official status in preventing the disease and should not be preferred over lifestyle management.

The comprehensive care of a diagnosed case of Type 2 diabetes, the survey of lifestyle habits and prophylactic lifestyle management and pharmacotherapy (e.g. dyslipidemia, hypertension) should clearly be monitored by a physician. Diabetes cannot be treated unless the patient assumes responsibility for treatment follow-up. A diabetes nurse plays a key role in monitoring and providing instructions on self-care. Multi-professional diabetes care units also employ other professionals (such as podiatrists, physiotherapists and dietitians). In the care of diabetes, the patient is guided towards assuming responsibility for the management and monitoring of the disease (self-measurement of blood sugar and blood pressure, regular weight monitoring).

Only guar gum is on offer for the OTC medicine therapy of Type 2 diabetes. The related therapeutic indications include the prevention of excessively high fasting hyperglycaemia and postprandial hyperglycaemia, and the supportive care of hypercholesterolaemia. Guar gum has only marginal significance in the care of the disease. Starting a patient on metformin, which according to the Current Care Guidelines is the basic Type 2 diabetes medicine, requires an evaluation and instructions issued by a physician. Supplementing the medication also requires a physician's assessment of the situation. Most type 2 diabetics on insulin are

instructed to adjust at least the dosage of their basal insulin and part of their bolus insulin dosage for themselves.

Type 2 diabetes is an example of a chronic disease in which self-care is of crucial importance, but in the case of which pharmacotherapy is largely under the supervision of a physician.

Addictive medicinal products

According to the EU criteria for OTC medicines, an OTC medicine must not cause addiction, nor may its consumption lead to abuse. For this reason, sleeping pills containing benzodiazepines, analgesics containing codeine and antiallergics or flu medicines containing pseudoephedrine are not included in the selection of OTC medicines.

Primary care of insomnia is non-medical. Overall, treatment of insomnia requires a good therapeutic relationship and monitoring, which are not possible through OTC care. Pain treatment requiring strong painkillers must be monitored by a physician.

Systemic antibacterial agents

Oral antibacterial agents, i.e. antibiotics, are used to treat diseases whose diagnosis is based on a medical examination of, and diagnostics related to, the patient. Even a physician may be unsure of the need for antibiotics, including in cases where there is a Current Care Guidelines recommendation for the suspected disease. Distinguishing a virus infection from a bacterial infection can be difficult, and antibacterial agents should not be used for virus infections. In OTC care, the use of systemic antibacterial agents can often lead to unnecessary or incorrect use, which can result in increased medicine resistance.

In Britain, single-dose azithromycin is available for the OTC care of a chlamydia infection, if a self-performed quick test is positive. From the Finnish viewpoint, this does not seem appropriate, since the differential diagnosis of genital chlamydia against genital infections caused by other pathogens must be performed by a doctor, as must the selection of the right medicine. The diagnosis and treatment of a chlamydia infection must also be entered in the patient records, which does not occur during self-care.

5 SAFE OTC MEDICATION

5.1 Properties required of OTC medicines

EU legislation and Finnish legislation on the classification of a medicinal product have not changed in the last few years. Fimea observes the valid regulations of the European Commission concerning the criteria for OTC classification.

In addition to individual and product level, the appropriateness of OTC medication should be evaluated at the population and therapeutic indication levels. This would take account of the direct and indirect advantages and disadvantages of OTC medicine from the perspective of the individual patient/consumer and public health. When evaluating a medicine proposed for OTC care, Fimea takes account of pharmacotherapy's position in the self-care of the disease in question. The national provisions for supplying and prescribing medicines can be employed in the risk management of OTC medicines.

More particularly, an OTC medicine must meet the following requirements:

An OTC medicine is effective and safe

- The medicinal product must have been proven to be effective and safe for the therapeutic indication, target group, dosage and duration of treatment for which the product has been approved for OTC care.
- In evaluating the risk-benefit ratio, the medicinal product proposed for OTC care is compared with corresponding medicinal products already approved for OTC care in Finland. However, the comparison does not include medicines, such as acetylsalicylic acid and paracetamol, which have been in OTC use before the entry into force of the current requirements on efficacy and safety.
- As a rule, the product must previously have been on prescription on the market for a sufficient time and in sufficient volumes, so that any risk of clinically significant, unforeseen or long-term hazards in OTC care can be ruled out.
- An OTC product may not affect the ability to drive or use machinery nor cause physical dependence, and must not cause withdrawal symptoms.

No significant, indirect harmful effects may result from the use of an OTC medicine

- The use of an OTC product must not substantially delay the diagnosis of an underlying condition or disease or any urgent treatment required by such a condition or disease.
- There may be no contraindications to the use of the OTC product that cannot be reliably identified during self-care.
- In addition, the possible adverse effects of the OTC medicine on necessary, non-medical treatment are considered an indirect hazard.
- In most cases, OTC medication is unsuitable for the treatment of a chronic disease requiring regular medical supervision in order to detect complications of the disease and for weighing up the treatment strategy.

OTC medicines require a wide safety margin, as their incorrect use is common

- With a medicinal product intended for OTC care, the anticipated adverse reactions of the active substance must mostly be mild.
- A dose of the medicinal substance must be such that a sufficient safety margin exists in the event of medication errors, such as mild overdoses or using the incorrect route of administration.
- The package size must be such that no unnecessary risk occurs of intentional or inadvertent poisoning.
- The product information must be easily understandable and readable, in order to diminish the possibility of incorrect use of the product.

- On the other hand, the risk of interaction between medicinal substances must be demonstrably small: the active substance may metabolise in the system only to a limited extent or via several routes, and may not inhibit or accelerate the effects in the system of other known medicinal substances to a clinically significant extent.
- A critical approach should be taken to the use of combination products in OTC care, due to possible interaction and the risk of inadvertent overdosing.
- The use of antimicrobial medicines must not contribute to the build-up of antimicrobial resistance.

5.2 Adverse OTC drug reactions

Although medicines used in OTC medicine must be sufficiently safe for self-care, as with any other medicines their use may involve adverse reactions. In most cases, the possible adverse effects – such as nausea, stomach complaints or fatigue – are mild and transient and are listed on the package leaflet.

As a rule, OTC products are intended for temporary use. Serious adverse reactions may still occur in connection with the use of some OTC medicines within a fairly short period of time, or near the upper limit of the recommended maximum dose. Examples of such products include acetylsalicylic acid, which can cause serious bleeding and even fatal cases of Reye's syndrome associated with viral infection, anti-inflammatory medicines which may cause bleeding in the gastrointestinal tract, and paracetamol which can cause severe liver damage. When a medicine is used contrary to the instructions on the package leaflet, the probability of adverse reactions increases. It can be difficult to suspect and identify adverse drug reactions unless the user actively finds out about the medicines he or she is using and their potential interactions.

Most medicines are either unsuitable for use during pregnancy, or no account has been taken of their safety during pregnancy. In OTC care, the consumer has responsibility for exercising sufficient caution during pregnancy and breast-feeding. Thus responsibility for taking account of possible interactions between medicines and of their compatibility lies ultimately with the consumer, as the pharmacy has no information on the customer's other medication unless the customer informs it of this.

5.3 Pharmacovigilance

The safety of the medicine is assessed prior to the granting of a marketing authorisation. A risk-management plan, which may include training and information packages as well as monitoring, is required from any marketing authorisation holder as a condition for the granting of authorisation. After marketing authorisation has been granted, safety is continuously monitored by means of adverse reaction records and research data. On the basis of new information, the summary of product characteristics and package leaflet can be updated if necessary, or the use of the medicine limited.

There is no difference between the safety monitoring of OTC and prescription drugs. Information on adverse drug reactions detected in Finland is gathered in Fimea's adverse reaction database, in which health care professionals and medicine users can report suspected or noted adverse reactions. Fimea relays information on all adverse reaction records it has received to the marketing authorisation holder of the suspected medicine and to the adverse reaction database of the World Health Organization (WHO), and also reports serious adverse reactions to EMA. Suspicions that new risks have arisen can lead to measures being taken when necessary, either nationally or at EU level, in order to safeguard the appropriate and safe use of the medicine.

5.4 Medication safety

Even the use of OTC medicines that are considered safe can involve problems if the medicines in question are not used as recommended. The packages, labelling and dosing instructions of medicinal products must facilitate the correct use of the medicine and prevent the danger of a mix-up with other medicines, for example. OTC selection should not include medicinal products that can be abused, say, for intoxication purposes. The package sizes of medicines that represent a poisoning hazard should not be large enough for overdosing to pose an immediate danger to life. When necessary, packages that are safe for children should be used.

In 2013, poisoning-related calls made to the Poison Information Centre mainly concerned paracetamol and ibuprofen, which are also available over-the-counter (**Table 2**). These statistics do not reveal how the medicine giving rise to the call was obtained, but do reveal that hazards can also be encountered in the case of familiar medicines commonly available in households.

Inappropriate or incorrect use of medicines undermines the results of pharmacotherapy, causes considerable health problems and increases the use of and costs incurred by health services. Medication errors can be prevented by means such as clear, easily accessible medicines information, counselling and advice.

Table 2. Most common calls reporting poison exposure from medicines in 2013 (n = 10 270). Source: Poison Information Centre.

Medicinal substance	Number of calls	%
Paracetamol	972	9.3
Ibuprofen	503	4.8
Quetiapine	428	4.1
Naproxen	298	2.8
Levothyroxine sodium	263	2.5
Oxazepam	195	1.9
Pregabalin	184	1.8
Codein + paracetamol	183	1.7
Venlafaxine	147	1.4
Citalopram	137	1.3

5.5 Challenges in safe OTC medication

Safe OTC medication requires that the medicine is used for the correct therapeutic indication, and only temporarily in most cases. In OTC care, assessment of the therapeutic indication is often based on the individual's assessment of his or her symptoms without a medical examination or diagnosis. Similar symptoms can, however, be related to various diseases. The challenge concerns whether the general public is able to make the medicine selections suitable for the situation in question, on the basis of the information and advice obtained from pharmacies.

When granting OTC medicine status, the authorities must consider the risks that may be associated with the use of an OTC medicine, including when it is used inappropriately. An easily accessible OTC medicine may tempt the individual to continue with the treatment longer than recommended, even where long-standing symptoms require a physician's assessment and further examination. In such a case, the diagnosis of a prolonged or serious illness may be delayed, which could affect the treatment results and prognosis.

A significant challenge to safe pharmacotherapy is posed by the fact that, during their purchase, OTC medicines are not registered in the health care databases or patient records. This means that no information on these is available to the physician or pharmacy. When a patient is seeking treatment, she may not recall the OTC medicines being used, or realise that s/he should inform medical staff of such medicines, unless s/he thinks they have a bearing on the reason for which s/he is seeking treatment. However, information on the OTC medicines used may be important to evaluating the patient's symptoms and care and determining what medicines, at what doses, the physician can prescribe for the patient. Tools intended for the public, such as various web services and medication cards, may help the patient to actively record his or her OTC medicines. However, such services reach only part of the general population at best, and the information registered in them is not necessarily available to the health care professional when providing treatment, writing a prescription or dispensing medicine.

6 DISTRIBUTION NETWORK FOR OTC MEDICINES, MEDICINES INFORMATION AND ADVERTISING OF MEDICINES

6.1 Pharmacies as retail distributors of OTC medicines

Finnish legislation allocates retail sales of medicines and the provision of medicine-related advice and services to pharmacies. In Finland, pharmacies have the sole right to dispense medicines to the public, with the exception of nicotine products and traditional herbal medicinal products. The following factors pertaining to the distribution system form the foundation for safe and rational OTC medication in Finland.

Pharmacy operations subject to a licence

Operating a pharmacy is subject to a licence. A pharmacy licence is granted by Fimea. In Finland, a pharmacy can only be owned by a licensed pharmacist (Master of Science in Pharmacy).

Dense retail distribution network

The retail distribution network for medicines consists of pharmacies, subsidiary pharmacies and pharmacy service points complementing pharmacy operations, particularly in sparsely populated areas. To ensure the availability of medicines, a pharmacy licence may lay down special terms on opening hours or on maintaining a subsidiary pharmacy or pharmacy service point. Pharmacies may also vend and dispense medicines via a web pharmacy service.

In the 2000s, the number of pharmacies has slightly increased (around 3%), whereas the number of subsidiary pharmacies has remained roughly the same (**Table 3**). Finland has one pharmacy outlet for every 6,500 or so residents. Finland's network of pharmacy outlets is denser than, e.g., in Sweden, Norway and Denmark. Fimea can decide on the establishment of a new outlet if the functioning of pharmaceutical services or availability of pharmacy services so requires. New pharmacies have been established in areas with increasing housing or service production, or in situations where the local authorities have considered an increase in pharmacy services in their area justified in order to safeguard the functioning of pharmaceutical services.

Table 3. Increase in the number of pharmacies, pharmacy service points and web pharmacy services.

	2000		2010	2011	2012	2013
Private pharmacies	593		616	618	614	614
Private subsidiary pharmacies	183		178	182	184	183
University pharmacies	2		2	2	2	2
Subsidiary pharmacies of university pharmacies	15		16	16	16	16
Pharmacy service points	-		-	22	36	55
Web services*	-		-	15	22	88

* Not all pharmacies reporting this information have initiated web services.

Trained staff

The pharmacy owner must ensure that a sufficient number of personnel qualified in pharmaceutical sciences (i.e. pharmacists) are employed in the pharmacy or subsidiary pharmacy. This requirement is based on Finnish legislation and has been the main reason for the high level of education among Finnish pharmacy personnel in European comparisons. The legislation concerning health care professionals extends to pharmacists.

It is the duty of every pharmacy owner to ascertain whether their personnel are participating in sufficient continuing education. By virtue of the legislation, health care professionals and pharmacists also have an obligation to maintain and develop their professional skills. Continuing education in support of high-quality medication counselling is of particular importance to ensuring the safe use of medicines, including OTC medicines. The obligation to participate in continuing education is monitored as part of Fimea's pharmacy inspections.

Views of the Finnish public regarding the availability of OTC medicines

According to a national survey conducted by Fimea in the spring of 2013, medicine users are satisfied with the availability of OTC medicines (Finnish Medicines Agency Fimea 2014a). 93% of respondents felt that OTC medicines were readily available, and 80% stated that pharmacies were located sufficiently nearby to provide them with easy access to OTC medicines (Table 4). Key criteria when deciding which pharmacy to use were location (88%) and opening hours (64%).

Table 4. Views of the Finnish public regarding the availability of OTC medicines (n = 2 210). Source: Finnish Medicines Agency Fimea 2014a.

Statement	Agree % (n)	Disagree % (n)	Neither agree nor disagree % (n)
OTC medicines are readily available	93 (2 060)	2 (45)	6 (105)
Pharmacies are located sufficiently nearby to provide easy access to OTC medicines	80 (1 763)	9 (202)	11 (245)
I have often been in a situation where I needed OTC medicines but the pharmacy was closed.	15 (325)	67 (1 488)	18 (397)
OTC medicines are not readily available on account of the scarcity of outlets retailing them.	10 (211)	72 (1 599)	18 (400)

6.2 Pharmacy as a provider of counselling on OTC medicine use

Pharmacists in pharmacies have a key role in the selection of OTC medicines and providing counselling on the correct and safe use of medicines.

The legislation requires that, by providing advice and instruction, pharmaceutical personnel in pharmacies strive to ensure that medicine users are aware of how the medicine should be used correctly and safely. Information must also be given on the prices of medicinal products and other factors influencing the selection of medicine. Medication counselling based on pharmaceutical expertise must also be given in the OTC and assisted self-service sections of any pharmacy.

Such counselling and advice must also take account of the fact that an OTC medicine does not always offer a solution to the patient's symptoms and that, in some situations, non-medical treatment may be a better option. It is particularly important to recognise situations where the patient's symptoms require referral to a physician. The advice given in a pharmacy must also take account of the possible use of products not classified as medicines, since such commonly merchandised products may also have adverse effects or interact with medicines.

Sales of OTC medicines through web pharmacy services and pharmacy service points pose their own challenges to medication counselling. In such cases too, users of OTC medicines must be provided with information on issues such as dosage, adverse reactions and interaction with other medicines.

A pharmacy must have the necessary information sources at hand in support of medication counselling, and its pharmaceutical personnel must have the ability to use them. Such information sources include portals commonly used in health care, various pharmaceutical databases, including databases on drug interactions, and the sources provided by various authorities. The Fimea regulation on dispensing medicines requires pharmacies to draw up a code of conduct on providing medication counselling (including OTC medicines).

Pharmaceutical personnel must report any observed or suspected adverse reactions pertaining to the use of medicines to Fimea.

Fimea supervises the operations of pharmacies and, by means such as inspections, determines how well pharmacies are adhering to the legislation steering their operations. A priority area in inspections has been the dispensing of OTC medicines, the related medication counselling, and the selection of OTC medicines and its comprehensiveness, including with regard to inexpensive products.

Views of the Finnish public regarding the counselling given by pharmacies

According to a national survey conducted by Fimea in the spring of 2013, medicine users are satisfied with the information obtained on OTC medicines and pharmacy operations (Finnish Medicines Agency Fimea 2014a).

The majority of respondents (85%) felt that the counselling on OTC medicines provided by pharmacies was adequate, and 84% said that they trusted the advice given by pharmacists (**Table 5**). 61% of the respondents wanted pharmacists to volunteer advice on how to use OTC medicines, while 28% said they usually preferred to buy medicines without advice from pharmacists.

Table 5. Views of the Finnish public regarding counselling on OTC medicines provided by pharmacists (n = 2 210). Source: Finnish Medicines Agency Fimea 2014a.

Statement	Agree % (n)	Disagree % (n)	Neither agree nor disagree % (n)
The pharmacy has sufficient personnel when I seek counselling on OTC medicines.	85 (1 876)	5 (108)	10 (226)
The information provided by pharmacies on OTC medicines is trustworthy.	84 (1 856)	2 (40)	14 (314)
I want a pharmacist to volunteer counselling on how to use OTC medicines.	61 (1 358)	13 (277)	26 (575)
The pharmacist also informs me of the most inexpensive alternative in any purchasing situation.	54 (1 203)	16 (362)	29 (645)
I usually prefer to buy medicines without counselling from a pharmacist.	28 (619)	36 (787)	36 (804)
Counselling provided by pharmacists on OTC medicines is difficult to understand.	3 (75)	81 (1 782)	16 (353)

89% of the respondents felt that the information available on OTC medicines was sufficient. 56% of the respondents contacted a doctor, a health centre or a child health centre if they were unsure of how to treat their symptoms. Meanwhile, the pharmacy was the primary source of information for 62% of the respondents if they were unsure of how to use the OTC medicine.

73% of the respondents felt that OTC medicines involved no risk when taken as instructed. 46% of the respondents were not concerned about adverse effects, and 56% found OTC medicines to be effective. These results relating to the public's risk assessments show that medication counselling and medicines information on OTC medicines is very important.

6.3 Medicines information relating to OTC medicines and the advertising of OTC medicines

The demarcation between medicines information and advertising of medicines can sometimes be difficult (**Figure 1**). Medicines information is neutral, trustworthy and unbiased information about medicines that does not strive to promote sales but to safeguard correct and safe use. The information referred to in Section 25, paragraph 2 of the Medicines Decree al-

so constitutes medicines information. Medicines information is not intended to favour one product. On the other hand, advertising of medicines entails information and activities promoting sales. The Medicines Act and Medicines Decree define specific marketing requirements with respect to focus of advertising, quality of the promotional information and hospitality requirements. Advertising of medicines covers various claims and sales pitches, including specific comparisons. Advertising promotes a single product.

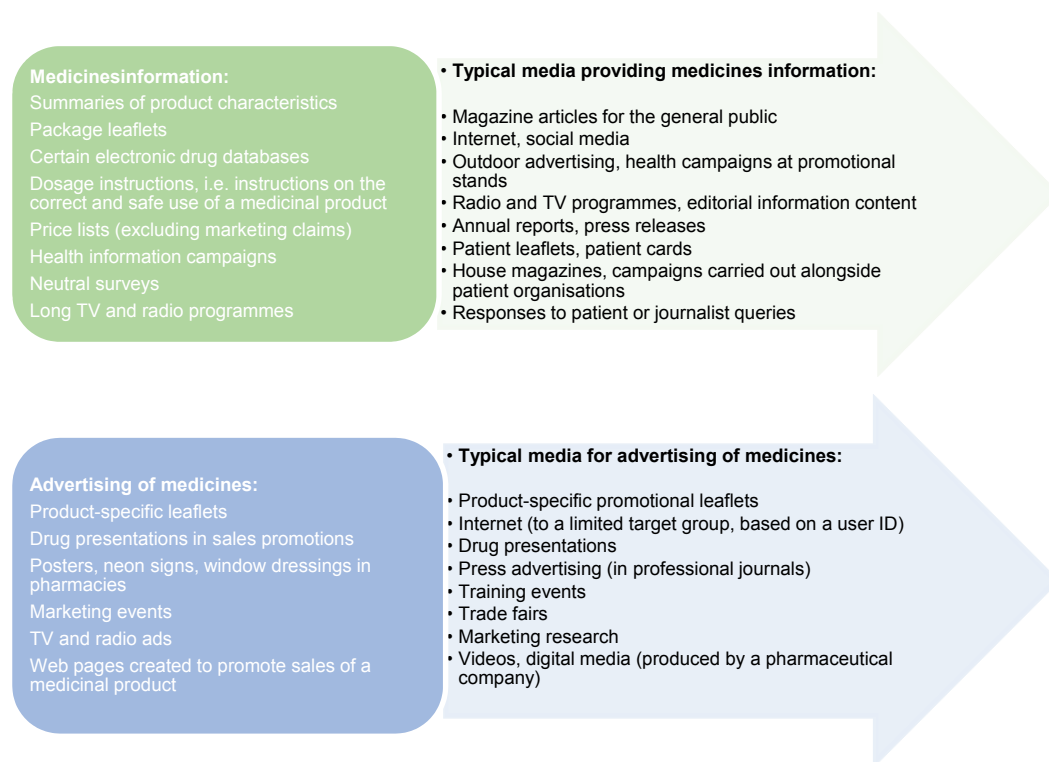


Figure 1. Medicines information vs. advertising of medicines.

6.3.1 Medicines information

As highlighted in the medicines information strategy (Finnish Medicines Agency Fimea 2012), many sources of medicines information are available to medicine users and patients. The key source is the counselling provided by health care professionals, particularly physicians and pharmacy professionals. According to national surveys, the package leaflet accompanying a medicine pack tends to be a key written source of information (Närhi 2007, Närhi and Helakorpi 2007, Holappa et al. 2012).

Use of the Internet as a source of medicines information has increased and will continue to do so: According to a national survey conducted in 2005, 20% of respondents had sought medicine-related information from the internet at some time in the last six months (Närhi 2007). According to an Internet survey conducted in 2014 and mediated to medicine users via patient and other organisations and pharmacies, 68% of respondents had used the internet as their source of medicines information at some point in the last year (Hämeen-Anttila and the "Medicines information for medicine users" -working group, 2014). In the future, the use of various mobile applications and other electronic services will also increase. Medicines information provides the basis for the rational use of medicines, thereby promoting the role of medicine users themselves in the care of minor ailments that can be easily self-treated, in accordance with the goals of the medicines policy (Ministry of Social Affairs and Health 2011a).

Finnish OTC medicines research has mainly concerned itself with medication counselling and medicines information (**Appendix 3**). On the other hand, most research of this kind is already over ten years old. Observation, mail surveys and interviews have been used as research methods. These studies have surveyed the opinions of both medicine users and pharmaceutical personnel on the success of medication counselling.

Studies conducted at the turn of the millennium found that pharmacy customers wished to obtain counselling on purchasing OTC medicines and that nearly all customers considered such counselling useful (Katajavuori et al. 2002, Kansanaho et al. 2002). This counselling was thought to have a positive effect on drug behaviour and understanding one's own medication (Kansanaho et al. 2002). However, no changes in counselling on OTC medicines were observed in the pseudo customer studies carried out during the project to the patient counselling in pharmacies carried out in 2000–2003 ("Appropriate information from the pharmacy for the benefit of the patient", TIPPA) (Puumalainen et al. 2005). According to a national survey conducted by Fimea in 2013, most respondents felt that the counselling on OTC medicines provided by pharmacies was adequate (Finnish Medicines Agency Fimea 2014a).

The customer service situation in the pharmacy also seems to have an effect on how actively pharmacists provide medication counselling (Lind and Kansanaho 2003, Katajavuori et al. 2002). In direct dispensing (prescription medicines), pharmaceutical personnel are more active, whereas in the assisted self-service section customers take the initiative and request medication counselling. Personnel's knowledge and attitudes may also affect the quality and content of counselling (Kurko et al. 2010). Professionals in pharmacy felt that providing counselling on nicotine replacement products remained the task of pharmacies after the sale of such products was permitted outside pharmacies (Kurko et al. 2009).

Published in 2012, the national medicines information strategy is a compilation of the views of stakeholders in the pharmaceutical sector on how medicines information should be developed. Account was taken of medication counselling on OTC medicines in the medicines information strategy, with respect to the main objective that "Medicines information is based on national recommendations and local agreements" under the separate requirement that "Medicines information on OTC care is ensured". Themes related to self-care are also considered under other objectives, and the strategy does not specifically differentiate between information on OTC medicines and prescription medicines. The OTC-related proposals for action made in the medicines information strategy are listed in **Table 6**.

Table 6. OTC-related proposals for action made in the medicines information strategy.

Proposals for action under the title "Ensuring medication counselling in self-care"	Support the work of professionals by producing evidence-based treatment guidelines concerning self-medication and self-care and integrate these into existing treatment guidelines wherever possible.
	Incorporate guidance for self-care and self-medication into the national self-care programme.
	Assess and monitor the quality of medicines information and medication counselling available from online pharmacy services and pharmacy service points.
OTC-related proposals for action under other headings	Define quality and structural standards for medication counselling and assess the possibility to document and monitor medication counselling.
	Further enhance package leaflet readability and contents in the EU.
	Produce medicines information in Swedish.
	Create a list of links to reliable sources of medicines information or establish a quality label.
	Develop and promote the visibility and participation of healthcare professionals in social media.
	Promote the use of the DARTS checklist, developed to help assess whether medicines information is reliable, among the public and in school teaching.
	Carry out a multidisciplinary population-level campaign on the safe and appropriate use of medicines.
	Ensure that the appropriate use of medicines and medicines information literacy continue to be included in the Core Curriculum for basic education.

Measures taken to improve medicines information relating to OTC medicines

The medicines information strategy identifies pharmaceutical personnel at pharmacies as being the key source of OTC medicines information, since in the case of mild symptoms the pharmacy is often the OTC customer's only contact with the health care sector. The skills of pharmaceutical personnel in giving self-care counselling have been developed for many years, for example via the joint national TIPPA project involving pharmaceutical sector

stakeholders, through which tools supporting OTC medication counselling were developed. Self-care counselling provided by pharmacies has been recently enhanced, for example in the "Check your choice!" project by the Association of Finnish Pharmacies. Self-care counselling skills are also taught as part of basic pharmacist education.

On the initiative of the medicines information network, a Current Care Recommendation for self-care will be drawn up to support pharmacists and other health care professionals in providing self-care counselling. On the initiative of the medicines information network, an article – "Medicines information on the internet" –has also been published in the Terveyskirjasto health-care library portal, to guide medicine users to sources of reliable medicines information.

The national multi-professional campaign for the correct and safe use of medicines, proposed in the medicines information strategy, has taken shape as part of National Medicines Day, launched on the initiative of Ms. Paula Risikko, Minister of Social Affairs and Health. The second National Medicines Day was arranged on 19 March 2014, based on a theme concerning the reasonable and safe use of OTC medicines. At that point, the aim was to activate medicine users into taking account of the use of OTC medicines as part of their overall medication and recording this in an up-to-date medication list. Furthermore, medicine users were guided towards sources of reliable medicines information.

The above measures were all aimed at promoting the critical health literacy of medicine users, which is also one of the objectives of the Pharmaceutical Policy 2020 statement and the medicines information strategy (Ministry of Social Affairs and Health 2011a, Finnish Medicines Agency Fimea 2012).

In addition, medicine education in schools, i.e. instruction in the correct use of medicines, has the aim of improving health literacy. Fimea has published a medicine education website, which is a revised version of the one originally created at the University of Eastern Finland (www.laakekasvatus.fi). Moreover, a project has been launched on the initiative of the medicines information network with the objective of intensifying co-operation between pharmacies and schools in medicine education. Pharmacy students are giving medicine education lessons as part of their pharmacy internship in 2014 and 2015.

It would also be crucial to increase the awareness and use of various tools for assessing the reliability of medicines information. One such tool is the DARTS checklist, with which the reliability of medicines information can be assessed (Finnish Medicines Agency Fimea 2014b). DARTS is an abbreviation based on the words for date, author, references, type, and sponsor.

6.3.2 General principles of advertising OTC medicines

OTC medicines may be advertised to the general population. The information content included in advertising must comply with the information given in the approved summary of product characteristics for the medicine concerned, and advertising may not tempt people to use medicines unnecessarily. Neither may the advertising of OTC medicines be associated with inducements or free gifts, competitions or discounts, bargains or preferential prices.

Pursuant to Section 91, paragraph 2 of the Medicines Act, it is emphasised with respect to advertising of OTC medicines that such advertising must not induce the population to use a medicine unnecessarily, give an erroneous or exaggerated idea of the composition, origin or pharmacological significance of the product, or be inappropriate in other respects.

A customary OTC medicine advertisement includes the trade name and active substance of the medicinal product, information necessary for the correct and safe use of the product and an easily legible request to carefully read the separate instructions on using the medicine. The efficacy of therapies may not be compared in product advertising.

An OTC medicine advertisement must include sufficient information on the correct and safe use of the medicine. Advertising of OTC medicines may not be targeted solely or principally at children. The advertising may not refer to recommendations by researchers, health care professionals or public figures, nor state that the medicinal product is a foodstuff, cosmetic product or other consumable.

Reminder advertising of OTC medicines means advertising which may only state the trade name of the OTC medicine, its international generic name or trademark, and the name of the marketing authorisation or registration holder. A reminder advertisement may not include

marketing claims, comparisons or other information. For example, the claims "quick-acting" and "inexpensive" are not allowed.

Health care professionals are capable of critically assessing the content of advertising of OTC medicines. In most cases, the same campaign information is targeted at both pharmacists within pharmacies and the general public. Fimea processes one or two cases a year involving an inquiry made about OTC medicine advertising targeted at health care professionals.

6.3.3 Monitoring of advertising

Fimea monitors the sector to ensure that medicine advertising is in accordance with the legal standards of the Medicines Act and Decree. Fimea intervenes in cases of illegal promotion of medicines, on the basis of errors or deficiencies in such advertising. Key areas monitored include the information content, target group and the moderation of any hospitality provided as part of advertising of medicines. Promotion of OTC medicines in various media is monitored ex-post. The monitoring process may also begin on the initiative of Fimea, which may itself be based on the initiative of a private individual. Aside from regulatory supervision, the pharmaceutical industry employs voluntary self-monitoring based on ethical guidelines. Such guidelines include detailed requirements on advertising of medicines and medicines information targeted at consumers and health care professionals (Pharma Industry Finland 2014).

Over the last seven years in Finland, Fimea and its predecessor, the National Agency for Medicines, have intervened around 60 times in cases of OTC medicine advertising considered contrary to the Medicines Act and Decree (**Table 7**).

In around half of such cases, a broader therapeutic indication than that approved in connection with the marketing authorisation for the medicinal product, or that stated in the summary of product characteristics, had been presented for the product.

Table 7. *Advertising contrary to the Medicines Act or Decree, in which Fimea has intervened in the last seven years.*

Advertising contrary to the Medicines Act or Decree	Number of cases
Presenting a therapeutic indication broader than that approved in connection with the marketing authorisation for the medicinal product, or engaging in otherwise misleading advertising	27
Inadequacy of information steering towards correct and safe use of the medicine	16
Bargain, preferential price or free gift	16
Total	59

Approximately one quarter of cases involving the monitoring of OTC medicine advertising related to deficiencies in information on the correct and safe use of the medicine in question. Intervention mainly concerned cases of so-called shelf talkers (attention grabbers affixed to shelf edges) and advertisements containing brief prompts to purchase the product. Intervention has equally often occurred in cases where an offer, preferential price, competition or free gift has been attached to advertising. In 2011, such cases mainly related to inducements offered via the web services of pharmacies, or free shipping attached to a large amount purchased. No inducements can be attached to the purchase of an OTC medicine, particularly in relation to the amount purchased. Errors relating to hospitality or the target group were uncommon.

Advertising of OTC medicines on TV and radio is permitted in Finland. In the last few years, ex-ante monitoring of TV and radio advertisements of OTC medicines has diminished and Fimea has drawn attention to the fact that advertisements include more objectionable content than before.

Drafting of OTC medicine advertisements requires that the authors are well-versed in the legal provisions concerning advertising laid down in the Medicines Act and Decree. The marketing authorisation holder is responsible for ensuring the legality of advertising.

7 EVALUATION AND DEVELOPMENT NEEDS OF APPROPRIATE OTC MEDICATION

7.1 Therapeutic indications suitable for self-care

As part of drawing up an OTC medicines programme, within their therapeutic area of responsibility Fimea's clinical evaluators investigated possible new therapeutic indications suitable for OTC medicines. Proposals from the pharmaceutical industry were examined in particular. **Appendix 2** shows examples of the possible risks posed by the medicines proposed for OTC use in the new fields of self-care put forward.

The following can be stated in conclusion.

- No new classes of medicinal substances were identified that were unreservedly suitable for OTC care.
- The survey is preliminary and its results do not affect the assessment of individual OTC applications. The risks highlighted in the survey must nevertheless be considered in the applications concerned.
- A fixed term for OTC classification would facilitate the approval of OTC medicines in cases where it is suspected that OTC classification causes safety-related or other problems.
- Major, widespread diseases, such as cardiovascular diseases and Type I and II diabetes, require comprehensive treatment and monitoring in which lifestyle counselling and monitoring of the disease's severity are emphasised. Broadening OTC medication to cover such diseases would introduce the risk of overemphasis of pharmacotherapy and targeting of the wrong patient groups.
- Furthermore, broadening the selection of anti-inflammatory medicines and enlarging their doses and package sizes would inevitably result in greater consumption and hence an increase in severe, even fatal, adverse reactions. When OTC classification is weighed up, the safety of the proposed product is therefore compared with that of the OTC medicines already approved.
- An increase in the use of medicine would not be equally problematic across all product groups suitable for OTC care.
- For example, the use of psychoactive medicines and hypnotics through self-care is not considered appropriate.
- Moreover, the approval of antimicrobial agents for OTC care would not usually be considered appropriate due to the risk of resistance.
- On the other hand, the availability of influenza vaccines without a prescription could improve vaccine coverage. However, at the moment EU legislation is not specifically favourable towards self-care with parenteral medicinal products, such as injectable vaccines. In the case of vaccines, possible decisions on the approval of medicines for OTC care should be planned as part of developing the tasks of different health care personnel.
- Potential risks do not necessarily prevent the approval of a medicine for self-care, in cases where the applicant can present a convincing risk management programme. Broadening the selection of OTC medicines requires sufficient capability to provide the required counselling on the expediency of self-care for the patient. In new areas of self-care, consultation of stakeholders must be considered on a case-by-case basis.

7.2 Measures for implementing safe OTC medicine

Increasing co-operation between pharmacies and other parts of the health care sector in providing guidance on self-care and the use of OTC medicines, and in managing pharmacotherapy as a whole

In accordance with the targets of Finland's medicines policy (Ministry of Social Affairs and Health 2011a), self-care should become more integrated with other aspects of health care. This will require co-operation between health care services and pharmacies. For physicians to take account of self-medication as part of overall patient care, both the physician and nurse need to be familiar with OTC products and with how the pharmacy provides guidance on self-care. Uniform medication counselling practices could also be agreed (Finnish Medicines Agency Fimea 2012). Care recommendations, product selections and counselling should be uniform and non-contradictory in pharmacies and health centres, as well as in health clinics and home care for the elderly (Ministry of Social Affairs and Health 2011b).

When safeguarding the safety of medication, it is crucial that OTC medicines be recognised as part of overall care. All of the parties concerned (the patient, health care service and the pharmacy) should be aware of what OTC medicines are being used by the patient – such information should be recorded on a medication list or electronic application, for example. On the basis of existing medication information, pharmacies must try to ensure that OTC medicines, particularly those used by chronically ill patients and patients on prescription medicines, are a suitable element of the patient's overall medication.

Improving the medication counselling provided by pharmacies in order to promote the correct and safe use of OTC medicines

Pharmacies and their pharmaceutical personnel are in a key position with respect to ensuring the correct and safe use of OTC medicines. Counselling on the use of OTC medicines and medicines information are not only a requirement for ensuring the safety of medication, they also constitute one of the rights of medicine users (Act on the status and rights of patients, August 18 1992/785, Section 5).

When arranging medication counselling, it should be noted that pharmacies have hugely varied clientèle, number of customers, premises and operations. All pharmacies must ensure that their personnel are suitably skilled and must upgrade their processes and premises in support of providing counselling to their clientèle. Pharmacies' physical design of premises must take account of the need to protect customer privacy during the discussion of sensitive issues related to pharmacotherapy.

Studies on patient counselling related to OTC medicines (**Appendix 3**) reveal that the provision of high-quality counselling in the assisted self-service section is challenging, particularly when the customer requests a medicine by its trade name. Insufficient research data has been gathered on the quality of medicines information and medication counselling provided by on-line pharmacies and pharmacy service points. Furthermore, up-to-date, published research data is required on the quality of OTC medicine counselling provided by pharmacies.

At national level, no quality standards are in place on the minimum level of medication counselling provided; such standards would harmonise counselling practices, including guidance on OTC medicines. The creation of quality standards for medication counselling has been proposed by the task force considering development needs with respect to pharmacy operations in out-patient care (Ministry of Social Affairs and Health 2011b), and such a need was also mentioned in the medicines information strategy (Finnish Medicines Agency Fimea 2012).

Increasing awareness of existing medicines information, and making better use of ICT and communication technology

Good sources of medicines information for medicine users and health care professionals are now available (Finnish Medicines Agency Fimea 2012). The challenge lies in promoting awareness and the use of existing information sources, rather than producing medicines information.

Health care professionals play a key role in promoting awareness of medicines information targeted at medicine users and in directing people to information sources. Furthermore, it is crucial that the health literacy of the general public be improved, so that when using medi-

cines people are able to seek reliable information and apply it to their personal circumstances (Ministry of Social Affairs and Health 2011b, Finnish Medicines Agency Fimea 2012).

The basic and continuing education of health care professionals is crucial to increasing awareness of good sources of medicines information aimed at professionals and to making use of such sources.

As information and communication technology evolves, it encourages patients and medicine users to assume responsibility for their therapy. It would be important to produce more medicines information in forms that reach medicine users.

Improving the usability of package leaflets

A medicine's package leaflet and labelling contain important information for OTC medicine users. However, such leaflets are not always highly usable. Moreover, differences in package leaflets for products containing the same active substance cause confusion among medicine users.

The information given on package leaflets is governed by common EU guidelines and marketing authorisation processes. The Finnish delegates on the EMA working groups developing the guidelines and Finland's experts engaged in the marketing authorisation processes are striving to facilitate the development of package leaflets, so that essential information on appropriate and safe use is conveyed effectively to the user.

Marketing authorisation holders play a key role in developing the legibility and intelligibility of package leaflets for OTC medicines. Although the guidelines for drafting package leaflets are relatively strict, the marketing authorisation holder can still influence the legibility of the package leaflet, particularly with regard to translations.

Ensuring the appropriateness of the content, scope and timing of advertising campaigns for OTC medicines

At best, the advertising of OTC medicines promotes the correct and safe use of medicines by providing an accurate picture of the product and its composition, origin or pharmacological significance. Advertising and medicines information which enhance the rational use of OTC medicines are to be encouraged in order to safeguard public health. The medicine regulatory authority considers full medicine advertisements to constitute better advertising than reminder advertising, which does not add to public awareness of the properties of an OTC medicine. For the general public, the most problematic issue lies in the difficulty experienced in comparing the properties of OTC medicines, since the advertising of such products does not necessarily include comparisons of their effects.

Over the last few years, advertising of OTC medicines targeted at health care professionals who are entitled to prescribe and dispense medicines has been appropriate, whereas more frequent interventions have been made in the case of overly aggressive or misleading advertising aimed at the public. To avoid excesses, the marketing authorisation holder must be able to appropriately delimit the content, scope and timing of advertising campaigns for OTC medicines. Fimea provides weekly advice to a range of stakeholders, in order to ensure the legality of advertising campaigns.

To produce advertising in line with the related legislation, it is essential to be familiar with the special characteristics of advertising of medicines. Marketing authorisation holders must also ensure that their employees are familiar with the related guidelines and have undergone internal training. Marketing authorisation holders bear responsibility for the advertising of all OTC medicines and must therefore assess the competence of third parties, i.e. the stakeholders they employ, such as advertising agencies and producers of TV or radio advertisements. In cases that have arisen during the monitoring of advertising, the underlying cause is often the advertiser's lack of familiarity with the legislation on medicines.

Voluntary monitoring of OTC medicine advertising by the pharmaceutical industry has changed over the last few years. These changes have increased the need for the medicine regulatory authority to monitor the advertising of OTC medicines. Some marketing authorisation holders do not engage in the voluntary monitoring of advertising.

In Fimea's view, ICT could be used as part of OTC medicine advertising to promote the correct and safe use of such products. On the other hand, rapid dissemination and publication of information will be risky in cases where not enough is known about the legal standards re-

lated to advertising of medicines. The new media enable better targeted marketing at less cost. Fimea monitors written, oral and digital advertising of medicines on the basis of the same legal standards. However, it is crucial to recognise the distinction made in the legislation between medicine-related communications, advertising and health information.

7.3 Finland's goals for the approval of OTC medicines under EU procedures

The position of OTC medicine is influenced by health care resources and structures, which vary by country. For this reason, Fimea does not view the harmonisation of OTC medicine as an end in itself, but as a process that proceeds within the framework permitted by the possible harmonisation of the health care systems of different countries. Hence, Fimea is not in favour of self-care decisions that are binding on Finland as part of the decentralised or mutual recognition procedure.

The European Commission can grant OTC status for a medicine, if the medicine has been assessed under the centralised marketing authorisation procedure. Decisions taken by the European Commission concerning OTC medicines are binding on Finland and harmonise Fimea's evaluation of other medicinal products containing the same active ingredient. This entails that decisions taken by the European Commission can affect entire product classes, if no essential differences exist between the medicines in the class concerned. EMA's OTC policy is just taking shape. Fimea is of the opinion that, under the centralised procedure, self-care decisions should be made binding on member countries solely with regard to OTC medicines that are significant to all member countries. Such medicines include products whose sufficient availability cannot be guaranteed, except by approving the medicine either permanently or temporarily for OTC care. A case in point would be medicines needed in connection with bioterrorism, pandemics and other states of emergency.

Finnish delegates should actively present the policies of the OTC medicine programme to expert groups that are crucial to OTC medicine, in order to achieve the widest possible recognition for Finnish policies. Particular care should be taken with respect to including the public health standpoint in the evaluation. In connection with the international processing of an OTC medicine application, it would be necessary to ascertain the suitability of a proposed OTC medicine for the Finnish health care system in particular.

8 CONCLUSIONS AND POLICY DIRECTIONS

Pharmaceutical services as part of social and health care

Pharmaceutical services form part of the social and health care system; this should be manifested in the monitoring and counselling of OTC medicine use.

- Pharmacies and local social and health care units should step up their co-operation in the monitoring and counselling of OTC medication.
- In accordance with the statement made in the medicines information strategy, local co-operation should be initiated in order to harmonise issues such as care recommendations, product selections and OTC counselling.
- To promote the up-to-date management of a patient's overall medication, the awareness and use of existing tools should be increased in co-operation with stakeholders within pharmaceutical sector and health care. This could be realised in, say, the activities of the inter-professional network and medicines information network at national level.
- All health care professionals should encourage patients to maintain an up-to-date medication list of their own medicines, on which they should also record their use of OTC medicines and nutritional supplements.
- Management of overall medication would improve substantially if information on the OTC medicines obtained by the patient were, at the patient's request and with his or her permission, recorded on the medication list via the Kanta patient data management service. This possibility should be investigated when developing the service further.

Broadening the selection of OTC medicines

From the public health viewpoint, OTC medicines are readily available in Finland in terms of hours, place and quantity. However, structural changes or lack of resources in health care may provide grounds for broadening the OTC medicine selection. In such a case, care must be taken to manage the associated risks. Particular attention should be paid to liability issues related to OTC medication and care pathways, to the appropriate use of OTC medicines, and to the safety of persons using several medicines simultaneously.

Policies enabling a controlled and safe OTC medicine selection and cutting health care costs:

- Fimea will separately evaluate OTC status applications for each medicinal product in question. When seeking OTC status for a product, marketing authorisation holders should take account of the properties required of OTC medicines pursuant to Section 5.1., the therapeutic indications suitable for self-care set forth in Section 7.1. and with respect to the risks that are outlined in **Appendix 2** in relation to possible new therapeutic indications. They should also present the measures by which such risks can be identified and diminished.
- The dispensing of individual OTC medicines can involve provisions, such as the supply of additional information, as a precondition for dispensing (an OTC medicine requiring additional advice – a behind-the-counter product, BTC). This is a risk management measure aimed at preventing the inappropriate use of a medicine. In such a case, Fimea will evaluate the content of the information package submitted by the pharmaceutical company and the capability of pharmacies to arrange counselling in the appropriate manner.
- After a medicine has been approved for OTC use, it is difficult to monitor its efficacy and safety. In the absence of reliable follow-up information, removing the medicine from self-care is difficult, even when its suitability for self-care is clearly questionable. This raises the OTC classification threshold. Granting an OTC licence only for a limited period can facilitate OTC decisions when it is difficult to assess the risk-benefit ratio with any certainty. In such a case, the marketing authorisation holder of

the OTC medicine may be tasked with the obligation to carry out risk management measures, for example monitoring the appropriateness of the medicine's use.

Harmonisation of OTC medicine within the EU

Finnish pharmaceutical experts work actively on the EMA, in task forces under the Council of Europe and on working groups within the European Commission, with the aim of ensuring that OTC medicine policy in the EU takes account of the public health viewpoint and self-care as a whole. Harmonising the selection of OTC medicines in the EU is not an end in itself, but should proceed while taking account of the member countries' variety of health care systems.

Medicines information and advertising of medicines

Fimea supports the target outlined in the Pharmaceutical Policy 2020 statement, of increasing the medicine user's role in the care of minor ailments that are easily self-treatable. This presupposes adequate counselling and rational medicines information promoting the use of OTC medicines. In the case of self-medication, the counselling and advice provided by pharmacists are emphasised. Responsibility for the selection and appropriate use of the medicine in question lies with the medicine user.

- Pharmacies should further improve their patient counselling on OTC medicines. The obligation to provide medication counselling laid out in the Medicines Act should also be fulfilled in assisted self-service and in counselling on the use of OTC medicines.
- In accordance with the proposal for action outlined in the medicines information strategy, the medicines information network should determine national standards on the quality and structure of medication counselling. These standards should take separate account of OTC counselling.

In improving medicines information, increasing awareness of existing medicines information plays a key role.

- Producers of medicines information should enhance its dissemination by means of digital communication. It is important that medicines information be provided in forms that can reach medicine users, while containing reliable content. Alongside electronic services, people should still be able to easily obtain the necessary counselling and advice in non-electronic forms.
- National co-operation on publicising and improving reliable and easily accessible medicines information should be continued as part of the activities of the national medicines information network.
- The legibility and contents of package leaflets should be improved so as to render their information clear and easily intelligible. Marketing authorisation holders play a key role in compiling package leaflets. For its part, Fimea is involved in improving the quality of package leaflets at EU level.
- Familiarity with the legislative provisions on and the special characteristics of advertising of medicines is essential when producing advertising in compliance with the related legislation and to understanding the difference between promotional advertising of medicines and neutral medicines information.
- Persons with responsibility for advertising of medicines must be familiar with the difference between information aimed at promoting sales and regarded as advertising, and medicines information. This is of particular importance when using digital communication media.

Research

Insufficient research has been done on how OTC medication affects the health behaviour of the population, the use of health care services and reduction of the load on health care.

Making decisions according to Finland's medicines policy requires the support of basic information and the latest follow-up data on OTC medicines in relation to:

- factors influencing the use of OTC medicine

- the appropriateness and safety of the use of OTC medicine
- the position of OTC medicine as part of overall care
- the current quality of patient counselling related to OTC medicine use
- the effectiveness of medication counselling and medicines information.

Conclusion

At best, OTC medicines can significantly improve the availability of medicines and, in many situations, lessen the load on the health care system. Finland's extensive pharmacy network and the highly educated staff in its pharmacies provide a good opportunity for the use of OTC medication in a more guided manner. This OTC medicines programme describes the current status and related development needs, while outlining policies for the future. Fimea would like the programme to provide a basis for a joint discussion within the pharmaceutical sector on how OTC medicine should be developed in Finland.

SOURCES

- Aaltonen K, Niemelä M, Norris P, et al. Trends and income related differences in out-of-pocket costs for prescription and over-the-counter medicines in Finland from 1985 to 2006. *Health Policy* 2013;110(2–3):131–40.
- Falah-Hassani K, Kosunen E, Shiri R, et al. Emergency contraception among Finnish adolescents: awareness, use and the effect of non-prescription status. *BMC Public Health* 2007;7:201.
- Finnish Medicines Agency Fimea. Rational use of medicines through information and guidance. Medicines Information Services: Current State and the Strategy for 2020. Serial Publication Fimea Develops, Assesses and Informs 1/2012. Kuopio: Fimea 2012.
- Finnish Medicines Agency Fimea. Views of the Finnish public regarding over-the-counter medicines – availability, risks and access to information. Serial Publication Fimea Develops, Assesses and Informs 1/2014. Kuopio: Fimea 2014a.
- Finnish Medicines Agency Fimea. Reliability of pharmaceutical information [cited 4.3.2014b]. www.fimea.fi
- Hakkarainen T, Airaksinen M. Kuuri loppuun! Lääkeneuvonnan opas. Kuopio: Fortis 2001.
- Halme M, Linden K, Kääriä K. Patients' preferences for generic and branded over-the-counter medicines. *The Patient* 2009;2(4):243–55.
- Heloma A, Ollila H, Danielsson P, et al. . Kohti savutonta Suomea – Tupakoinnin ja tupakkapolitiikan muutokset. Terveystyden ja hyvinvoinnin laitos. Teema 16, Tampere 2012.
- Holappa M, Ahonen R, Vainio K, et al. Information sources used by parents to learn about medications they are giving their children. *Res Soc Adm Pharm* 2012;8(6):579–84.
- Hämeen-Anttila K, working group Lääkeinformaatiota lääkkeiden käyttäjille. Medicines information needs and sources – a population survey for medicine users. Serial Publication Fimea Develops, Assesses and Informs 2/2014. Kuopio: Fimea 2014.
- Kansanaho H, Isonen-Sjölund N, Pietilä K, Airaksinen M, Isonen T. Patient counselling profile in a Finnish pharmacy. *Patient Educ Couns* 2002;47:77–82.
- Katajavuori NM, Valtonen SP, Pietilä KM, et al. Myths behind patient counselling: a patient counselling study of non-prescription medicine in Finland. *JSAP* 2002;19(4):129–36.
- Kurko T, Linden K, Pietilä K, et al. Community pharmacists' involvement in smoking cessation: familiarity and implementation of the National smoking cessation guideline in Finland. *BMC Public Health* 2010;10:444.
- Kurko T, Linden K, Vasama M, et al. Nicotine replacement therapy practices in Finland one year after deregulation of the product sales – Has anything changed from the community pharmacy perspective? *Health Policy* 2009;91:277–85.
- Lind L, Kansanaho H. Itsearviointiraportti apteekin lääkeneuvonnan kehittämisen apuna. *Dosis* 2003;19:51–64.
- Ministry of Social Affairs and Health. Medicines Policy 2020. Towards efficient, safe, rational and cost-effective use of medicines. Helsinki: Publications of the Ministry of Social Affairs and Health 2011:10eng. textual reference: (Ministry of Social Affairs and Health 2011a)
- Ministry of Social Affairs and Health. Development needs regarding outpatient pharmacy operations. Helsinki: Reports of the Ministry of Social Affairs and Health 2011:16. textual reference: (Ministry of Social Affairs and Health 2011b)
- Närhi U. Sources of medicine information and their reliability evaluated by medicine users. *Pharm World Sci* 2007;29:688–94.
- Närhi U, Helakorpi S. Sources of medicine information in Finland. *Health Policy* 2007;84:51–7.
- Pharma Industry Finland. Pharma Industry Finland Code of Ethics [cited 4.3.2014]. www.pif.fi
- Puumalainen II, Peura SH, Kansanaho HM, et al. Progress in patient counselling practices in Finnish community pharmacies. *Int J Pharm Pract* 2005;13:149–56.

Sihvo S, Gissler M, Närhi U, et al. Vähensikö jälkiehkäisyn reseptivapaus raskaudenkeskeytyksiä? *Suom Lääkäril* 2003;58:2452–5.

Sihvo S, Klaukka T, Martikainen J, et al. Frequency of daily over-the-counter drug use and potential clinically significant over-the-counter-prescription drug interactions in the Finnish adult population. *Eur J Clin Pharmacol* 2000a;56:495–9.

Sihvo S, Ahonen R, Mikander H, et al. Self-medication with vaginal antifungal drugs: physicians' experiences and women's utilization patterns. *Fam Pract* 2000b;17:145–9.

Stakes. Lääkehoidon kehittämiskeskus Rohto. Potilas- ja lääkehoidon turvallisuussanasto. Helsinki: Stakes, Työpape-reita 28/2006. Turunen JHO, Mäntyselkä PT, Kumpusalo EA, et al. How do people ease their pain? A population-based study. *The Journal of Pain* 2004;5(9):498–504.

Turunen JHO, Mäntyselkä PT, Kumpusalo EA, et al. Frequent analgesic use at population level: Prevalence and pat-terns of use. *Pain* 2005;115:374–81.

World Health Organization. The rational use of drugs. Report of the Conference of Experts Nairobi, 25–29 November 1985. Geneva: WHO 1987.

APPENDICES

APPENDIX 1. Definitions.

Self-care

Self-care denotes an individual's voluntary activity aimed at health maintenance, and alleviating the symptoms or curing a disease. Rational use of OTC medicines forms part of self-care (Ministry of Social Affairs and Health 2011a). The most common form of self-care is self-medication. Aside from OTC medicines, this includes the use of products other than medicinal products (alternative products, such as nutritional supplements and health care devices).

OTC medicine

An OTC medicine means a medicine that can be dispensed from a pharmacy without a prescription (Decree by the Ministry of Social Affairs and Health on the prescription of medicines 1088/2010).

Rational pharmacotherapy

Rational pharmacotherapy means that the patient receives the correct medicines at the correct time, uses them appropriately and benefits from them (World Health Organization, 1987).

OTC medicine requiring additional advice (behind-the-counter, BTC)

An OTC medicine for which marketing authorisation can be obtained, on condition that the requirement for additional information on the basis of the material supplied by the marketing authorisation holder is met. OTC medicines on which additional advice must be given can also be supplied by an Internet pharmacy or pharmacy service point, but steps must be taken to ensure that the additional personal advice is given and documented before the medicine is dispensed. This kind of product is often also referred to as a BTC (behind-the-counter) product.

Medicine

A medicine denotes a product or substance used internally or topically, with the purpose of curing, alleviating or preventing a disease or its symptoms from occurring in humans. A product or substance used internally or topically to determine a person's state of health or the reason for his or her illness, or for restoring, remedying or altering vital functions is also considered a medicine (Decree by the Ministry of Social Affairs and Health on the prescription of medicines 1088/2010).

Medicines information

Medicines information denotes information on medicines and pharmacotherapy that is available to consumers and health care professionals from various information sources, either in person, in written form or via electronic services (telephone, Internet, television and radio etc.). Medicines information is produced by the authorities, health care professionals, the pharmaceutical industry and patient organisations, for example. Medicines information includes information relating to the medicinal product and the use of the medicine, as well as medication counselling (Ministry of Social Affairs and Health 2011b, Finnish Medicines Agency Fimea 2012). The purpose of medicines information is not to promote sales, but to ensure the correct and safe use of medicines.

Medicines information strategy

A document drawn up and published by Fimea, broadly based on interviews with and the opinions of operators in the pharmaceutical sector, describing the present status of medicines information activity and its development needs up to 2020 (Finnish Medicines Agency Fimea 2012).

Medicines Information Network

The objective of the medicines information network established in 2012, the national network for all stakeholders in the pharmaceutical sector, is to increase national and international multi-professional co-operation in order to produce reliable information on medicines and the related services, to raise awareness of such information and services, and to assess their impact. Such activities are based on the national medicines information strategy to be put into practice in development projects by working groups. The network is coordinated by Fimea in co-operation with the medicines information coordination group. Other working groups within the network include the research working group, education working group, the Medicines information for professionals working group and the Medicines information for medicine users working group.

Medication counselling

A consultation between a customer or patient and a health care professional, in which the professional helps the customer to cope with pharmacotherapy, while simultaneously taking account of the customer's personal needs (Hakkarainen and Airaksinen 2001, Ministry of Social Affairs and Health 2011a).

Drug safety

Drug safety mainly involves safety in relation to a medicinal product (Statistics Finland and Centre for Pharmacotherapy Development Rohto). Drug safety includes the demonstrated pharmacological efficacy and safety of the medicinal product, and its pharmaco-chemical quality, product markings and product-related information.

Medication safety

Medication safety means safety relating to the use of medicines (Statistics Finland and the Centre for Pharmacotherapy Development Rohto 2006). This covers the principles and activities of individuals and organisations acting within health care, the purpose of which is to ensure the safety of pharmacotherapy and to protect the patient from harm. This also includes the prevention, avoidance and reversal of adverse reactions relating to the use of medicines.

Availability of medicines

The availability of medicines can denote several phenomena of different levels. In this OTC medicines programme, the availability of medicines refers to a sufficiently broad selection of medicinal substances being available for therapeutic indications suitable for OTC care and, when necessary, the rapid and easy availability of OTC medicines for use by medicine users in geographical (sufficiently dense pharmacy network), temporal (opening hours of pharmacies) and economic terms (reasonable price, generics).

Self-care

An approach promoting adherence to treatment, in which the patient is steered towards taking responsibility for his or her care. This includes measures for maintaining and promoting health, and the follow-up and care of symptoms, by means of which the effects of the disease on the patient's capacity, emotions and social life are managed (Ministry of Social Affairs and Health 2011a).

Food supplement

A food supplement denotes a readily packaged product sold in an extrudate, capsule, lozenge, tablet, pill, powder, concentrate, extract, liquid or other corresponding form of dosage that is marketed as a foodstuff, is consumed in small, measured doses and releases an amount of energy of no dietary significance. The purpose of a food supplement is to com-

plement the patient's diet based on its specific nutrients or other ingredients, or to influence a person's nutritional or physiological functions in other ways. A food supplement does not mean a product classified as a medicine under the Medicines Act (395/1987) (Decree by the Ministry of Agriculture and Forestry on food supplements 78/2010).

Prescription medicine

A prescription medicine denotes a medicine that can be dispensed from a pharmacy on prescription only (Decree by the Ministry of Social Affairs and Health on prescription of medicines 1088/2010).

Health care device

Health care device denotes an instrument, equipment, device, software, material or other device or accessory that the manufacturer has intended for use in a) the diagnosis, prevention, monitoring, treatment or alleviation of a disease, b) the diagnosis, monitoring, treatment, alleviation or compensation of a disability or handicap, c) the examination, compensation for or alteration of an anatomic or physiological function, d) the regulation of conception in a person (Act on health care devices and equipment 24.6.2010/629). When a device is brought into the market, it must be provided with a CE marking indicating that it meets the essential requirements set for such devices.

APPENDIX 2. Examples of medicinal substances and/or therapeutic indications proposed for OTC care but not yet accepted, and of the possible risks.

Therapeutic indication	Active substance	Potential risk
Acute urinary tract infection	trimethoprim, pivmecillinam	Differential diagnosis between venereal diseases and a urinary tract infection requires laboratory diagnostics.
Allergic rhinitis (systemic combination products)	acrivastine + pseudoephedrine	Combination product. This could be problematic due to e.g. the impairment of the ciliary function, which is essential for clearing the mucous membranes in the respiratory tract, and the harmful effects of long-term use on the cardiovascular system. Abuse may also occur.
Asthma		Differential diagnosis of asthma from other lung diseases, for example, may be difficult. This is a chronic disease that requires monitoring and careful control.
Bacterial infections	antimicrobial products	If the number of topical antibiotics in self-care is broadened, the result could be the emergence of antibiotic resistance. It is not possible to select the correct antibiotic without an examination.
Diabetes		Continuous monitoring of therapy is essential and should be reflected e.g. in clinical records.
Erectile dysfunction	e.g. sildenafil	The hazards related to the simultaneous use of nitro are great (collapse of blood pressure) and a physician's evaluation is needed. Self-care could delay or prevent the diagnosis of e.g. coronary disease. Received a negative opinion on OTC status from the EMA.
Benign prostatic hyperplasia		Prostatic cancer diagnosis may be delayed.
Genital herpes		Careful examination of the patient is essential to confirming the diagnosis and ruling out other, simultaneous infections.
Influenza vaccine		This is a parenterally administered medicine. It is not clear how administration of the medicine is organised. At the moment, the health care system offers an influenza vaccine to high-risk groups. Vaccination coverage must not be compromised.
Gout		Gout requires a physician's assessment and laboratory diagnostics.
Pain management	diclofenac	Liver and cardiovascular impairment has been observed during short-term use.
Hypertension		Continuous control of blood pressure is essential and requires regular monitoring by a physician and assessment of the treatment through laboratory tests and electrocardiogram tracking. In the case of OTC care, the problem may be that the importance of e.g. exercise and weight management is disregarded.
Prevention of malaria		Resistance to malaria medicines is increasing, which needs to be taken into account when selecting a medicine.
Migraine	triptans	The diagnostics of severe illnesses resembling migraines in terms of their symptom profiles may be delayed, and there is a greater risk of adverse effects on cerebral and cardiac blood vessels. A negative opinion on the proposed OTC status of sumatriptan has been issued by the EMA.
Rheumatoid arthritis	e.g. glucosamine, chondroitin sulphate	This is a chronic illness. Treatment requires the correct diagnosis and the monitoring of medication. The therapeutic value of glucosamine and chondroitin sulphate is being re-evaluated.
Psoriasis	calcipotriol, strong cortisones	This is a chronic, long-term skin disease that may be associated e.g. with Type 2 diabetes requiring additional monitoring. The root causes of skin diseases must be determined as precisely as possible.
Contraception		It is important to assess the risk of thrombosis. Requires monitoring.
Conjunctivitis	chloramphenicol, fusidic acid	The problem lies in the differential diagnostics between an allergic and infectious inflammation of the eye. For example, herpes ceratitis requires rapid treatment with an antiviral medicine. It is not possible to select the correct antibiotic without an examination. Inappropriate increase in consumption is also a risk. In Britain, the release of chloramphenicol eyedrops for OTC care in 2005 increased package-specific overall sales (prescription + OTC) by nearly 50% in three years.
Prophylaxis of cardiovascular diseases	simvastatin	Patients may be left without the best possible care. At population level, patients may be directed to OTC care who do not benefit from such treatment. Evaluation of the need for therapy, guidance in non-medical therapy, monitoring and follow-up cannot be carried out at a pharmacy. It is not considered possible for a patient to evaluate the natural course of cardiovascular diseases. Simvastatin has several interactions with many common medicines.
Leg ulcers		Many diseases can lie in the background of leg ulcers, and these diseases must also be treated.
Difficulty in sleeping	benzodiazepams	Care of insomnia requires a good care relationship and monitoring. The problem may also be improper use and substance abuse.
Menopausal complaints	estriol	Individual evaluation of the risk of breast cancer is important. Requires monitoring.
Cough		The problem lies in distinguishing a harmless cough from e.g. an infectious or chronic cough. A chronic cough requires more detailed examination. The efficacy of cough medicines is often questionable. With respect to children, the elderly or patients who are chronically ill in particular, the use of cough medicines should be considered carefully.

APPENDIX 3. Finnish original research on OTC medicines published in the 2000s and 2010s, with main results
Theses, reviews or reports are not included.

Reference	Methods	Main results
Use of OTC medicines		
Linden K, Jormanainen V, Swigonski NL, et al. Self-medication among Finnish young men in the beginning of common military service. <i>Pharmaco-epidemiol Drug Saf</i> 2005;14:193–201.	Survey of conscripts (n = 857, response rate 95%) in 1999 The use of medicines obtained without prescription during the last two weeks for the following symptoms: headaches, other pain, rhinitis, temperature or a sore throat, coughs, skin symptoms, sleep disorders or anxiety, stomach pains or constipation, was defined as self-medication. In addition, the use of stimulants such as caffeine tablets, and the use of vitamins or trace elements or self-medication for symptoms other than those stated above, was regarded as self-medication.	65% of the men had used self-medication in the two weeks preceding the survey. 54% of the respondents had used OTC medicines for pain or the common cold, and 8% had used caffeine tablets or other stimulants. More frequent self-medication for pain or the common cold was connected with secondary education, health which had been self-reported as good or excellent, and experiencing pain. Furthermore, the prevalence of self-medication varied in accordance with the location in which the respondent was performing his military service. The use of stimulants was related e.g. to trying illegal drugs.
Kause M, Vainio K, Ahonen R. Neli-vuotiaiden lasten kuumeen kotihoito. (Home care of temperature in four-year-old children.) <i>Dosis</i> 2000;16(2):130–8.	A survey of the parents of four-year-olds who attended a child health centre for the health inspection for 4-year-olds (n = 86; 83 mothers, 3 fathers; response rate 86%) Turku in 1991	Pharmacotherapy was most often used to treat temperatures. 88% of the children had received antipyretic medicine. Use of the medicine was begun when the temperature was 37,5–40,0 degrees. The most common antipyretic was paracetamol. According to the responses given by the parents, the selection of an antipyretic was chiefly influenced by a recommendation from a physician (46%), pharmacy personnel (16%) or a public health nurse (15%). 85% of the parents stated that use of the antipyretic provided no clear benefit.
Oksama H, Sihvo S, Pietilä K. Jälkiehkäisy itsehoitona. Käyttäjäkysely apteekin asiakkaille. (Emergency contraception as self-care. User survey for pharmacy customers.) <i>Suom Lääkäril</i> 2004;59(46):4507–11.	Survey of all those who obtained emergency contraceptives from outlets of the University Pharmacy in September–October 2003 (n = 447, response rate 48%)	The largest user group for emergency contraceptives was 20–24-year-olds. The key reason for purchasing this product was lack of contraception. 46% of the respondents stated that they were under the influence of alcohol at the time of intercourse. 64% of the respondents had used emergency contraceptives previously (one fifth at least three times). Most emergency contraceptives were purchased during the weekend. The most important sources of information on emergency contraception were the media (81 %) and friends (61%) (physician 19% and pharmacy 18%). However, 91% of the respondents stated that they had read the package instructions or patient leaflet.
Sihvo S, Ahonen R, Mikander H, et al. Self-medication with vaginal antifungal drugs: physicians' experiences and women's utilization patterns. <i>Fam Pract</i> 2000;17:145–9.	The purpose of the study was to investigate the appropriateness of self-medication of a vaginal yeast infection, by seeking the views of women who use such self-medication and those of physicians. The survey was distributed between 20 pharmacies in different parts of Finland in 1997 (n = 299, response rate 66%). A postal survey of gynaecologists and general practitioners, a representative random sample in 1996 (n = 341, response rate 77%)	Almost all respondents had used an antifungal medicine previously: 49% of the women had done so during the last six months. Most respondents did not report any problems in the use of the antifungal medicine, but 44% used the medicine contrary to the recommendations. Half of the women reported symptoms that were probably due to infections other than Candida. The physicians reported several drawbacks in self-medication: the most frequently mentioned were unnecessary use and use for the wrong therapeutic indication. 31% of gynaecologists and 16% of general practitioners responded by indicating that such drawbacks were clinically significant. The most frequently cited, clinically significant problem was a delay in providing the correct care (12%).
Sihvo S, Klaukka T, Martikainen J, et al. Frequency of daily over-the-counter drug use and potential clinically significant over-the-counter-prescription drug interactions in the Finnish adult population. <i>Eur J Clin Pharm</i> 2000;56:495–9.	Survey "Health behaviour of the population" in 1995–1996 (n = 5 171, response rate 86%)	17% of the respondents had used OTC medicines and 15% had used vitamins obtained over the counter during the two days preceding the survey. 7% of the respondents used OTC medicines daily and 9% used vitamins. Constant use of OTC medicines was connected with higher age, being female in gender, having a higher education, self-assessed poor health, long-term morbidity, psychosomatic symptoms and the use of prescription medicines, but was not connected to an unhealthy lifestyle. 4% of OTC medicine users had used medicine combinations that potentially led to significant interaction.

Taskinen J, Päljänoja O, Ahonen R. Onko itsehoitosärkyä lääkkeiden myynti ongelma apteekissa – kipujen ja särkyjen itsehoito farmaseutin ja proviisorin näkökulmasta. (Are sales of OTC painkillers a problem at pharmacies – self-care of pain and aches from the viewpoint of a pharmacist.) <i>Dosis</i> 2002;18(2):91–7.	Survey of pharmacists of three pharmacies (n = 24) in the autumn of 2000	More than half of the respondents stated that, at least once a week, they encountered situations in which they wanted to intervene in a customer's use of OTC painkillers. The situation is often exacerbated by the fact that the customer is offended, or it is feared that he or she will be offended, by such intervention. In most cases, the respondents wished to counsel a customer in situations associated with suspicion of the continuous use of painkillers. In the respondents' opinion, the efficacy of the medicine was the key criterion when a customer selected a painkiller.
Turunen JHO, Mäntyselkä PT, Kumpusalo EA, et al. How do people ease their pain? A population-based study. <i>The Journal of Pain</i> 2004;5(9):498–504.	Population study of 15–74-year-old Finns in 2002 (n = 4 542, response rate 71%) The report involved the analysis of responses from respondents who had experienced pain during the last week (n = 3 641).	The most commonly used pain management methods were OTC medicines (53%), exercise (52%), prescription medicines 35%) and a visit to a physician (33%). The use of several treatments was associated with prolonged pain, experiencing more than one type of pain, the intensity of the pain and its recurrence.
Turunen JHO, Mäntyselkä PT, Kumpusalo EA, et al. Frequent analgesic use at population level: Prevalence and patterns of use. <i>Pain</i> 2005;115:374–81.	Population study of 15–74-year-old Finns (n = 4 542, response rate 71 %) in 2002 Those respondents who reported using painkillers daily or a couple of times a week were classified as frequent users of painkillers.	The prevalence of daily analgesic use was 8.5% and a couple of times a week 13.6%. The prevalence of the use of painkillers only obtained over-the-counter daily or a couple of times a week was 8.8%. Combined use of a prescription and OTC painkiller daily or a couple of times a week accounted for 4.6% of the respondents. Those using painkillers often report daily or continuous pain and severe pain. Also, a low mood and unemployment were connected with daily analgesic use.
Medication counselling and medicines information related to OTC medicines and the advertising of OTC medicines		
Halme M, Linden K, Kääriä K. Patients' preferences for generic and branded over-the-counter medicines. <i>The Patient</i> 2009;2(4):243–55.	Survey directed at university students (n = 256) on the selection of an original medicine and generic medicine (ibuprofen)	Half of the respondents considered price to be the key factor influencing a purchase decision. Other factors included the brand and the possibility to obtain the advice of a physician or a pharmacist in the pharmacy.
Kansanaho H, Isonen-Sjölund N, Pietilä K, et al. Patient counselling profile in a Finnish pharmacy. <i>Patient Educ Couns</i> 2002;47:77–82.	Telephone survey of customers (n = 200, response rate 100%) in the autumn of 1996 Survey of the pharmaceutical personnel of a single pharmacy (n = 15) of a counselling situation (n = 558) Pharmacists recorded information on issues such as the initiator (customer or pharmacist) and the approximate duration and content of counselling for each counselling situation taking place during the course of six days.	Almost all (97%) customers felt that the medication counselling was useful. 31% of the respondents felt that the counselling had a positive effect on the use of medicines. 36% of the respondents understood their medication better (for example, why and how to use their medicine, although there was no change in behaviour). 30% of the respondents felt that the counselling had no effect on the patient's taking the medicine. Counselling on adverse reactions was given in more than half (65%) of the situations. In most cases, the initiator of the counselling was the pharmacist (70%) Pharmaceutical personnel seemed to be more active in counselling prescription customers (82 of cases) than OTC customers (37% of cases).
Katajavuori NM, Valtonen SP, Pietilä KM, et al. Myths behind patient counselling: a patient counselling study of non-prescription medicine in Finland. <i>JSAP</i> 2002;19(4):129–36.	Observational study on a purchase and counselling situation of an OTC medicine (n = 869) Pharmacists systematically offered assistance to customers in the self-care section. Focus group interview of pharmacists (n = 3) at a shopping centre pharmacy in 1999	The myth that customers do not want advice was shown to be incorrect; only a minority of the customers rejected the assistance offered (7%). In 53% of the observed situations, the pharmacist gave instructions on where the medicine was to be found. In 40% of the observed situations, the pharmacist gave advice related to pharmacotherapy, for example on the duration of the effect, the care of the disease or symptom or the use of the medicine. If the customer requested the medicine by name, medication counselling was usually not given (17% of customers who requested the medicine by name obtained counselling on pharmacotherapy). On the other hand, if the customer requested help due to a certain symptom, 94% received counselling relating to pharmacotherapy.
Kauppinen-Räsänen H. The impact of extrinsic and package design attributes on preferences for non-prescription drugs. <i>Management Research Review</i> 2010;33(2):161–73.	16 consumers were asked to talk about their preferences in regard to analgesics and medicines intended for the care of a sore throat, and regarding the properties of the accompanying packaging.	Taste was an important factor in medicines intended for the care of a sore throat, as were the package's colour and the manufacturer. In the case of painkillers, the manufacturer and package colour are most highly valued. In the case of painkillers in general a known manufacturer is considered to be the most important feature, whereas in the case of medicines intended for the treatment of a sore throat the key issue is a domestic manufacturer.

<p>Kurko T, Linden K, Pietilä K, et al. Community pharmacists' involvement in smoking cessation: familiarity and implementation of the National smoking cessation guideline in Finland. BMC Public Health 2010;10:444.</p>	<p>Survey of pharmacy owners and pharmaceutical personnel in pharmacies (n = 1 190, response rate 54 %)</p>	<p>Almost half (47%) of the respondents were familiar with the Current Care Guideline on smoking cessation.</p> <p>Familiarity with the Current Care Guideline was connected with the respondents' notion of his or her skills and knowledge of smoking cessation (OR 3.8), their notion of the significance of nicotine replacement advice to the customer (OR 3.3) and the use of a pocket card supporting cessation advice (3.0).</p> <p>Those familiar with the Current Care Guideline were more likely to recommend methods of supporting smoking cessation other than NRT products, than those who were unfamiliar with the guideline.</p>
<p>Kurko T, Linden K, Kolstela M, et al. Is nicotine replacement therapy overvalued in smoking cessation? Analysis of smokers' and quitters' communication in social media. Health Expect. 2014;8. (Epub ahead of print, doi: 10.1111/hex.12280)</p>	<p>Content analysis of discussions related to smoking cessation and nicotine replacement therapy (NRT) on the STUMPPPI Internet forum in 2007–2012 in five forum rooms (n = 24 481 discussions)</p>	<p>Three main themes were recognised in the discussion</p> <ol style="list-style-type: none"> 1) distrust and a negative attitude towards the use of NRT products 2) neutral acceptance of NRT products in support of smoking cessation 3) trust in the key role of NRT products in smoking cessation. <p>Behind the negative attitude was the notion that NRT products maintain nicotine dependency, the fear of dependency caused by NRT products and poor experiences of NRT products (the products have not helped in smoking cessation).</p> <p>On the other hand, NRT products were also viewed as important, particularly when smoking cessation is initiated and in managing psychological dependence. In the discussions, empowerment and support offered by loved ones were viewed as important factors in successful smoking cessation.</p>
<p>Lamminen S, Airaksinen M. Itsehoitovalmisteiden pakkauselosteiden luettavuus. (Legibility of package leaflets of OTC products.) Dosis 2005;21(2):154–63.</p>	<p>The study was conducted in 1999</p> <p>Package leaflets of three commonly used OTC product groups Analgesics: ASA, ibuprofen, dexibuprofen, ketoprofen, paracetamol Abdominal medicines: famotidine, ranitidine, sucralfate Antiallergics: acrivastine, beklometasone dipropionate, sodium cromoglycate, cetirizine dihydrochloride (n = 63 package leaflets, of which 18 are identical package leaflets and 50 are leaflets with various contents)</p> <p>In accordance with the Tekstut legibility test, the package leaflets were divided into easy to read and difficult to read, and a content analysis was performed on all of them.</p> <p>Scale for Tekstut legibility values: 0–35 very easy text, 35–44 easy language, 44–60 normal language, 60–68 difficult language, 68–100 very difficult text.</p> <p>In the content analysis, the package leaflets were studied by comparing them to regulatory requirements, and special attention was paid to the reporting of adverse drug effects.</p>	<p>Half of the package leaflets studied were written in normal language and the remainder either in easy or very easy language.</p> <p>The factual content of the package leaflets was not directly dependent on the Tekstut legibility value. On the other hand, a high Tekstut legibility value did not guarantee a good package leaflet in terms of the contents.</p> <p>The Tekstut readability analysis indicated that none of the package leaflets were extremely difficult to read on the whole, and the legibility of the package leaflet was not necessarily compromised by containing a high amount of information.</p> <p>The sections of the package leaflets that were easiest to understand were dosing (37.8), pregnancy and nursing (41.6), mode of action (43.9) and purpose of use (46.5).</p> <p>The most difficult sections to understand in the package leaflets were contraindications (50.7), safeguards (54.8), interaction (57.2), side effects (57.3) and special warnings (58.8).</p>
<p>Lind L, Kansanaho H. Itsearviointiraportti apteekin lääkeuuvonnan kehittämisen apuna. (Self-evaluation report as a tool for developing medication counselling in a pharmacy.) Dosis 2003;19:51–64.</p>	<p>Observation study on customer situations (n = 416) in 2001</p> <p>Group interview study on pharmaceutical personnel (n = 6)</p>	<p>Medicines information was provided in three ways:</p> <ol style="list-style-type: none"> 1. formally, in the form of a pharmacist's monologue 2. adapted to customer needs as a dialogue between the pharmacist and the customer (mainly in the form of medication counselling to long-term users) 3. in a customer-oriented manner emphasising equality between the customer and the pharmacist (counselling on OTC medicines). <p>The pharmaceutical personnel were more active in direct dispensing (82%) situations and the customers more active in assisted self-service (61%) situations.</p> <p>In direct dispensing situations, the topics most discussed were medicine dosage instructions (61%), the duration of the medication (36%) and adverse drug reactions (30%).</p> <p>On the OTC side, the topics most discussed were the purpose of the medicines (39%), dosage instructions (28%) and referral of the patient to a physician.</p>

<p>Puumalainen II, Peura SH, Kansanaho HM, et al. Progress in patient counselling practices in Finnish community pharmacies. <i>Int J Pharm Pract</i> 2005;13:149–56.</p>	<p>Pseudo customers study (n = 960) v. 2000–2003</p> <p>Convenience sampling in 60 pharmacies, four different customer cases, 240 contacts yearly</p> <p>Included three self-care scenarios and one prescription medicine scenario.</p> <p>The tool used for quality assessment was based on the recommendations of the United States Pharmacopeia.</p>	<p>In two of the four scenarios, medication counselling improved to a statistically significant extent during the follow-up period.</p> <p>Viewing the improvement of self-care advice as a whole, no change was observed in counselling.</p> <p>Counselling was scant with respect to previously dispensed prescription medicines and when a medicine was requested by name.</p>
<p>Rajamäki H, Katajivuori N, Pietilä K, et al. The smokers' perception of health care personnel advice to quit smoking. <i>J Soc Adm Pharm</i> 2003;20:64–71.</p>	<p>Postal survey in three locations in southern Finland, random sample (n = 1 800, response rate 44–49 %) in 1999</p>	<p>Most of the respondents viewed the written material and advice provided by a physician as the best ways of obtaining information on smoking cessation.</p> <p>No information or advice on smoking cessation was obtained from pharmacies. In general, there could be a clear increase in the level of activity of health care professionals (physicians, dentists, nurses and professionals in pharmacy) when providing advice.</p>
<p>Salminen M. Asiakaskysely apuna Tippa-projektin käynnistämiseksi Nummelan apteekissa. (Customer survey in support of the launch of the Tippa project Nummela pharmacy.) <i>Dosis</i> 2001;17:81–90.</p>	<p>Interview of pharmacy customers (n = 151) in 2000.</p>	<p>About one third of prescription medicine customers and one tenth of OTC customers stated that they obtained counselling on their medicine during the dispensing situation preceding the interview.</p> <p>In most cases, advice was provided on the effects and use of the medicine, with adverse reactions being discussed more seldom.</p> <p>Customers receiving the medicine for the first time were given advice more often than those who had used the medicine earlier (30% in prescription medicines vs. 17% and 21% vs. 6% in OTC medicines).</p> <p>13% were dissatisfied with the lack of counselling.</p>
<p>Turunen JHO, Mäntyselkä PT, Ojala RK, et al. Public's information needs on analgesics: A descriptive study in a drug information centre. <i>Int J Pharm Pract</i> 2008;16(2):91–7.</p>	<p>Of the calls received at the Kuopio drug information centre (KLIK), questions relating to the use of analgesics were analysed for a period of two years (1.9.2002–31.8.2004) (n = 2 683)</p>	<p>Two thirds of the questions related to the use of analgesics by women and 19% to the use of analgesics by children under the age of 16.</p> <p>Callers mainly asked about interaction (35%), dosage (15%), pain management and increasing efficacy (9%) and the effects of analgesics (8%).</p> <p>Most of the questions were about paracetamol (24% of calls), ibuprofen (23%), coxibs (15%) and naproxen (14%).</p> <p>The content of the inquiries varied somewhat according to the medicinal substance.</p>
<p>Use of OTC medicines by children and adolescents and the factors influencing this</p>		
<p>Hämeen-Anttila K, Englund A, Ahonen R. Miten usein koululaiset käyttävät itsehoitolääkkeitä? Kyselytutkimus kuopiolaisille koululaisille. (How often do schoolchildren use OTC medicines? Survey of schoolchildren in Kuopio.) <i>Dosis</i> 2005;21(3):180–8.</p>	<p>Survey conducted in schools in Kuopio, grades 5 and 8 and grade 1 in senior high school in 2003 (n = 183, response rate 91 %)</p>	<p>54% of the pupils stated that they had used OTC medicines to treat some symptoms during the last week.</p> <p>Headaches (38%) and temperatures (11%) were the most frequently treated symptoms.</p> <p>7% stated that they use OTC medicines daily (mainly for allergies and pain relief and to improve their haemoglobin levels).</p> <p>Most had received the medicines from their parents.</p> <p>Schoolchildren acquired information on medicines from many different sources, mainly from their mothers (87%).</p>
<p>Hämeen-Anttila K, Lindell-Osuagwu L, Sepponen K, et al. Factors associated with medicine use among Finnish children under 12 years. <i>Pharmacoepidemiol Drug Saf</i> 2010;19:400–7.</p>	<p>Population survey for parents of children under 12 (n = 4 032, response rate 67 %) in 2007</p>	<p>The prevalence of OTC medicines in children under 12 was 17 % (excluding vitamins).</p> <p>Factors predicting the use of OTC medicines were low age, health assessed as being fairly good or poor and the use of OTC medicines by a parent. However, a child for whom a disease had been diagnosed by a physician used less OTC medicines.</p>
<p>Hämeen-Anttila K, Halonen P, Siponen S, et al. Parental attitudes toward medicine use in children in Finland. <i>Int J Clin Pharm</i> 2011;33:849–58.</p>	<p>Population survey of parents of children under 12 (n = 4 032, response rate 67 %) in 2007</p>	<p>15% of the parents who responded had reservations about medicine use. 84% considered prescription medicines to be safe and effective, whereas 49% considered OTC medicines to be safe and effective.</p> <p>69% of the respondents were worried about risks of medicines, particularly those parents who were over the age of 46, were less educated and used complementary or alternative therapies themselves, and whose children had a chronic illness. Furthermore, 46% of the respondents were worried about the long-term use of analgesics.</p> <p>Parents who used OTC medicines had a more positive attitude towards medicine use in general compared to parents who did not use OTC medicines themselves. They also had a more positive attitude towards long-term use of analgesics.</p>

Hämeen-Anttila KP, Niskala UR, Siponen SM, et al. The use of complementary and alternative medicine products in preceding two days among Finnish parents – a population survey. <i>BMC Complement Altern Med</i> 2011;11:107.	Population survey of parents of children under 12 (n = 4 032, response rate 67%) in 2007	31% of the respondents had used a complementary or alternative product during the two days prior to the survey. The most commonly used complementary and alternative products were vitamins and trace elements, and fish oil products. The group most commonly using complementary and alternative products was women slightly over 30 with a high level of education. Those using complementary and alternative products had a more negative attitude towards medicines than respondents who do not use such products.
Niskala U, Ylinen S, Pääkkilä H, et al. Täydentävät ja vaihtoehtoiset hoitomuodot lasten itsehoidossa – vanhempien kokemuksia. (Complementary and alternative therapeutic approaches to the self-care of children – parents' views.) <i>Dosis</i> 2009;25(4):186–96.	Population survey of parents of children under 12 (n = 4 032, response rate 67 %) in 2007 This study analysed those comments written on the back leaf of the questionnaire that mentioned alternative and complementary therapies in the medication of children. 32% of the respondents wrote free-form comments on the back leaf of the questionnaire and 9% of all respondents (n = 343) described alternative and complementary therapies. Qualitative content analysis and quantification	Complementary and alternative therapies mentioned by the parents included home remedies (n = 127), herbal remedies and nutritional supplements (n = 91), alternative therapies (n = 76), vitamins and trace elements (n = 68), lactic acid bacteria and functional foods (n = 45), a healthy lifestyle (n = 47) and common sense (n = 17). Herbal remedies and nutritional supplements were most often said to have been used for the care of various pains and colds. Few spontaneous comments were made on efficacy. The parents more often commented on the relief that complementary and alternative therapies brought to the child's symptoms than the possible ineffectiveness of such treatments.
Siponen SM, Ahonen RS, Kettis-Lindblad A, et al. Complementary or alternative? Patterns of complementary and alternative medicine (CAM) use among Finnish children. <i>Eur J Clin Pharm</i> 2012;68:1639–45.	Population survey of parents of children under 12 (n = 4 032, response rate 67%) in 2007	The prevalence of the use of complementary and alternative medicine (CAM) for children under 12 years of age was 11%. The CAMs most often used were fish oil products (6%) and probiotics (4%). The use of CAMs was predicted by the child being the family's first, the use of vitamins, and experiencing at least one symptom. Furthermore, use of CAMs and vitamins by a parent was connected to the use of CAMs by a child. 7% of respondents reported that the child had used CAMs in connection with a prescription or OTC medicine in the last two days.
Siponen S, Ahonen R, Kiviniemi V, et al. Association between parental attitudes and self-medication of their children. <i>Int J Clin Pharm</i> 2013;35(1):113–20.	Population survey for parents of children under 12 (n = 4 032, response rate 67%) in 2007	The parent's positive attitude towards OTC medicines was connected to the use of OTC and prescription medicines by the child. Concern by the parent about the risks associated with medicines predicted the use of alternative and complementary therapies on the child. The use of alternative and complementary therapies was smallest in children whose parents had a positive attitude towards the use of prescription medicines.
Ylinen S, Hämeen-Anttila K, Sepponen K, et al. The use of prescription medicines and self medication among Finnish children under 12 years of age. <i>Pharmacoepidemiol Drug Saf</i> 2010;19(10):1000–8.	Population survey of parents of children under 12 (n = 4 032, response rate 67%) in 2007	50% of the children had used some form of self-therapy: an OTC medicine (17 %), vitamins (37%) or complementary and alternative therapies(11%). The OTC medicines most commonly used were analgesics and antipyretics (7% of the children). Paracetamol was the most commonly used OTC medicine (5%). D-vitamin was the most commonly used vitamin (20% of the children).
Classification change of prescription medicines as OTC medicines		
Aalto-Setälä V, Alaranta A. Effect of deregulation on the prices of nicotine replacement therapy products in Finland. <i>Health Policy</i> 2008;86:355–62.	Price information on nicotine replacement products from pharmacies, groceries, kiosks and service stations (n = 2 106)	The prices of nicotine replacement products fell by 15% on average following deregulation. Around half of the price reduction was due to the abolition of the pharmacy fee in NRT products, and half was due to price competition. Although the cheapest products are available from supermarkets, pharmacies offer the widest selection.
Falah-Hassani K, Kosunen E, Shiri R, et al. Emergency contraception among Finnish adolescents: awareness, use and the effect of non-prescription status. <i>BMC Public Health</i> 2007;7:201.	Survey of Finnish girls aged 12–18 in 1999, 2001 and 2003 Response rates: 1999: 83% (n = 4 369) 2001: 79% (n = 4 024) 2003: 77% (n = 3 728)	Almost all girls aged 14–18 and the majority of those aged 12 knew about emergency contraception in 2001. The change in the classification of emergency contraceptives from prescription medicines to OTC medicines had no bearing on such knowledge. 9% of girls aged 14–18 had used emergency contraceptives once and 1% three times or more often. Approval of emergency contraception as an OTC medicine had no effect on the quantities of emergency contraception used. Alcohol use, smoking, dating, poor performance at school and living somewhere other than in a nuclear family were connected with the use of emergency contraception.

<p>Kiviluoto K, Sjöblom A, Ylinen V. Behind-the-counter-lääkkeet: uhka vai mahdollisuus? (Behind-the-counter medicines: threat or opportunity?) <i>Dosis</i> 2014;30(1):23–36.</p>	<p>Semi-structured pilot interview in 2014 of professionals in pharmacy (n = 3) and consumers (n = 3), charting opinions on BTC medicines and their suitability in Finland.</p> <p>Exemplary medicines used in the interview: naproxen, chloramphenicol eye drops, pseudoephedrine, simvastatin, sumatriptan, tamsulosin, adrenalin pen.</p>	<p>Higher availability of medicines, fewer visits to the physician and cost savings in health care were viewed as the advantages of the behind-the-counter class of medicine.</p> <p>Incorrect use or abuse of medicine – whether intentional and unintentional – increasing antibiotic resistance and lack of control by physicians were viewed as drawbacks.</p> <p>The researchers emphasise that, on account of the small sample, the results cannot be generalized.</p>
<p>Kurko T, Linden K, Vasama M, et al. Nicotine replacement therapy practices in Finland one year after deregulation of the product sales – Has anything changed from the community pharmacy perspective? <i>Health Policy</i> 2009;91:277–85.</p>	<p>The aim of the study was to chart pharmacists' notions about the role and use of NRT products one year after deregulation (transfer to grocery stores).</p> <p>Questionnaire for pharmacists (n = 1 190, response rate 54%)</p>	<p>In the opinion of the respondents, the incorrect use of NRT products (dependency, abuse) can be seen in Finland.</p> <p>The respondents reported that sales of NRT products at pharmacies had diminished. It was also reported that customers visit pharmacies to obtain advice on the use of NRT products but buy the products from grocery stores.</p> <p>Motivation for providing advice on the use of NRT products had declined by 30% among pharmacy owners and by 17% among pharmacists.</p> <p>However, the respondents considered the provision of advice on the use of NRT products to be the duty of a pharmacy.</p>
<p>Kurko T, Silvast A, Wahlroos H, et al. Is pharmaceutical policy evidence-informed? A case of the deregulation process of nicotine replacement therapy products in Finland. <i>Health Policy</i> 2012;105:246–55.</p>	<p>Document analysis of all publicly available documents related to the deregulation of nicotine replacement products in the legislation process in 2006 (total 402 pages).</p> <p>Furthermore, 12 Members of Parliament were interviewed in spring 2006.</p>	<p>Deregulation of the sale of nicotine replacement products (NRT) had been presented to the political decision-makers as a safe intervention which increased smoking cessation and thereby improved public health. However, most interest groups had argued against deregulation. No evidence-based information has been presented in support of the public health justification with respect to sales of mere NRT products without the related advice and counselling.</p>
<p>Närhi U, Vanakoski J, Sihvo S. Switching of H(2)-Receptor Antagonists to Over-the-Counter Status in Finland: Implications for Consumption and Adverse Effects. <i>Clin Drug Investig</i> 2005;25(4):243–8.</p>	<p>Medicine consumption statistics Adverse drug reaction database</p> <p>H2 receptor antagonists (A02BA), proton pump inhibitors (A02BC), sucralfate (A02BX02) and antacides (A02A) were studied.</p> <p>Adverse drug reactions reported with respect to H2 receptor antagonists and proton pump inhibitors in the years 1990–2003 were studied using the adverse drug reaction database.</p>	<p>Between 1990 and 2003, the use of medicines for upper abdominal complaints (oesophageal reflux disease and peptic ulcer disease) more than doubled.</p> <p>Approval of ranitidine and famotidine for OTC care in 1996 increased the consumption of such medicines.</p> <p>However, proton pump inhibitors were the most commonly used medicine: they accounted for 75% of the total consumption of medicines used for the treatment of oesophageal reflux disease and peptic ulcer disease (22.2 DDD / 1 000 people / day).</p> <p>Approval of ranitidine and famotidine for OTC care did not increase the number of adverse drug reaction reports related to these medicines.</p>
<p>Rainio SU, Huhtala HS, Rimpelä AH. Use and acquisition of nicotine replacement therapy products among underage adolescents after deregulation of the sales. <i>Nicotine Tob Res</i> 2010;12(8):870–3.</p>	<p>Population survey of adolescents of 12–18 years of age (n = 5 840, response rate 61%) in 2007 (one year after the deregulation of nicotine replacement products)</p>	<p>2% of 14-year-old boys and 2% of girls had used nicotine replacement products.</p> <p>7% of 16-year-old boys and 5% of girls had used nicotine replacement products.</p> <p>10% of 18-year-old boys and 8% of girls had used nicotine replacement products.</p> <p>One quarter of 12-year-old girls and 15% of boys of similar age did not know what nicotine replacement products were. Knowledge of these products increased with age.</p>
<p>Sihvo S, Hemminki E, Ahonen R. Physicians' attitudes toward reclassifying drugs as over-the-counter. <i>Med Care</i> 1999;37:518–25.</p>	<p>Postal survey of gynaecologists and general practitioners (n = 341, response rate 77%), representative random sample in 1996</p>	<p>The general attitude of physicians towards the availability of OTC medicines was fairly positive.</p> <p>Their attitude towards medicines that had recently acquired OTC status was more cautious.</p> <p>Physicians were also regarded as the most suitable source of medicines information with regard to advice on OTC medicines.</p> <p>Compared to other physicians, physicians working in health centres considered medicines available for OTC use to be more suitable for self-care.</p> <p>The hypothesis according to which gynaecologists would object to antifungal agents being transferred to OTC care was not confirmed.</p>

<p>Sihvo S, Gissler M, Närhi U, et al. Vähensikö jälkikäisyn reseptivapaus raskaudenkeskeytyksiä? (Did the OTC status of emergency contraception increase the number of terminations?) Suom Lääkäril 2003;47:2452–5.</p>	<p>Database study Abortion figures for 2001 and 2002 were obtained from the termination register maintained by Statistics Finland. Sales figures for emergency contraceptives for 2001 and 2002 were obtained from the manufacturer.</p> <p>Emergency contraceptives were released for use as OTC medicines on 1 May 2002.</p>	<p>In 2002, sales of emergency contraceptives increased by 62% on 2001 (from 45 080 packages to 73 245 packages).</p> <p>Sales of the only OTC product almost quadrupled (from 16 731 packages to 66 139 packages); in 2002, sales of this product accounted for more than 90% of total sales of emergency contraceptives.</p> <p>The number of abortions increased among women and girls under 25 years of age in 2002 compared to 2001, and fell among women aged 25–29 years.</p> <p>In early 2002, there were more abortions than in 2001, but towards the end of the year their number decreased on the previous year, and in the last quarter fewer abortions were performed than in the same quarter in the previous year.</p> <p>The number of abortions among 15-19-year-olds began to decline in the second half of the year. More abortions were performed on 20–24-year-olds in each quarter than in the previous year.</p> <p>Based on this information, the researchers conclude that OTC status does not provide a solution to the large number of abortions.</p>
<p>Other</p>		
<p>Aaltonen K, Niemelä M, Norris P, et al. Trends and income related differences in out-of-pocket costs for prescription and over-the-counter medicines in Finland from 1985 to 2006. Health Policy 2013;110(2–3),131–40.</p>	<p>In cross-sectional studies of household income and expenses (Household Budget Survey) in 1985, 1990, 1995, 2001 and 2006, the out-of-pocket costs of prescription and OTC medicines were calculated (OOP = out-of-pocket costs) (n = 4 007–8 258, response rate 52–70%).</p>	<p>Households' medicine costs increased across the entire observation period.</p> <p>The growth in costs was steepest between 1990 and 1995: households' OTC medicine costs increased by 69%. Between 1995 and 2001, the corresponding growth rate was 32%</p> <p>In relative terms, the lowest income classes paid more for their medicines (prescription and OTC medicines) than the higher income classes.</p>



Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

PL 55, 00034 FIMEA | Street addresses: Helsinki, Mannerheimintie 103b | Mannerheimintie 166, Helsinki (Laboratory) | Mikrokatu 1, Kuopio