

# Lääkeinformaatiota Lääkelaitokselta



Läkemedelsinformation från Läkemedelsverket, Finland

Drug information from the National Agency for Medicines, Finland

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## Novel processes created by electronic prescribing

Electronic prescriptions introduce significant improvements in the controlling of drug treatment. In the new system, the prescription is prepared electronically and thereafter transferred via data networks to the prescription centre. The pharmacy has the task of supplying the patient with the prescribed medicine in accordance with the information received from the prescription centre, and is responsible for the drug information associated with supplying it to the patient.

The use of electronic prescriptions makes it possible to review the patient's entire medication already at the stage of prescribing and thereby to better the quality of drug treatment. It improves the evaluation of the drug treatment of the patient and avoids any drug interactions. The changeover diminishes unnecessary work at the pharmacy. The pharmacy no longer needs to rewrite the instructions already once written by the doctor. Hand-written prescriptions continue in the 21st century to cause misinterpretations at pharmacies. These prescriptions are also documents which are very easy to forge. The importance to the patients of the changeover lies in the fact that they no longer need to walk to the pharmacy with a prescription in their hand. The system also gives the patient a choice to choose, since the prescription may be collected from any pharmacy. It is also easier for the patient to check the validity of the prescriptions and the quantity of unsupplied drugs.

It rings a bell – it is a familiar development. As late as in the 1980's I was still physically taking my green deposit book to the bank for the credit and debit to be recorded. Then the banking business changed form and we entered the electronic era which in the 21st century has developed into the modern electronic banking system. Money transactions are still made on my bank account, and I am regularly keeping an eye on the situation and making payment orders. I have my own personal contact at my bank, and the contact person is available should problems arise or should I want to discuss my financial concerns. The last time I remember having visited a bank was when signing documents for a house mortgage.

I should think that, like me, there are several other people of my generation who will find it difficult in the future to justify a visit to the pharmacy every three months. A prescription, information about a drug and checking a reimbursement entitlement by the Social Insurance Institution are not sufficient grounds. Starting a new drug treatment and receiving the associated information are natural causes for a visit, but while the drug treatment continues I would appreciate even other alternatives. I think I would be content with an annual medical examination and having the support of a pharmacist specializing in drug information. I am not denying that there would still be a great number of patients in Finland who would continue to value their visits to the pharmacy very highly indeed.

Pharmacy operations ought to develop with a focus on the new conditions under which they operate, the changing environment and the patients' new expectations. Electronic prescriptions create the facilities for the electronic pharmacy services described above. This new way of providing pharmacy services requires a transfer of the pharmacy operations to the electronic environment and the development of new models of logistic operations. As a business model this bears resemblances to the rest of e-commerce. In pharmacy operations the most relevant difference is of course the requirement for drug information. Direct drug information from the pharmacist to the patient is naturally the most efficient type, but situations exist where the new lines of action evidently achieve an adequate and acceptable level of service from the patient's point of view.

The pharmacy working group set up by the Ministry of Social Affairs and Health in Finland has discussed the position and the development of the pharmacy institution. Electronic pharmacy services are a totally new service option, the development of which still requires a solution to the question of how the logistic part of the electronic pharmacy services could be appropriately arranged in the professional pharmacy system.

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## A joint effort in medicines education

*Medicines education became part of the comprehensive school health education curriculum along with the reformed basis of the curricula in Finland in 2004 (1). Teachers are nevertheless unfamiliar with the subject and it is not clearly defined in the foundations of the curricula. Medicines education is mentioned in the primary school discipline known as nature and environmental education for year-classes 1–4 as follows: 'the pupil should be familiar with the basic rules governing the use of medicines'; and in the health education discipline of the secondary school it says: 'the pupil should be familiar with the basics of the appropriate use of medicines'. It is clear that teachers should be given the means to carry out medicines education and teach it in practice.*

In order to assist teachers in their work, an appropriate website for medicines education in comprehensive schools was set up in the Department of Social Pharmacy at the University of Kuopio in Finland ([www.uku.fi/laakekasvatus](http://www.uku.fi/laakekasvatus) partly in English). The web pages were designed as part of my dissertation, as a project for Master of Pharmacy students (2). Five comprehensive school teachers participated as experts.

The website about medicines education contains plenty of independent current information about the use of medicines. As an aid in the planning of the teaching and based on research results we have set out plans for lessons to be given at various class levels (3). To facilitate the practical introduction of teaching we also prepared complete ready-to-use teaching lesson plans. During my study, 14 comprehensive school teachers tested the usability of the first version of the medicines education pages. Based on their critical comments the web pages were redesigned and provided with a completely new image (4). The present medicines education website is updated twice a year.

In order to render the medicines education more concrete we defined its aims as follows: to teach children to become sensible users of medicines, to make

children prepared to talk with a doctor and at the pharmacy about issues involving the use of their own medication and to understand the purpose of medicines in the treatment of diseases and as prophylactic measures. The aim is also to promote critical and evaluative thinking. Children should learn to search for information about medicines and assess the reliability of the information they have found. This is especially important in the era of the Internet.

The underlying current in the medicines education pages is the ideology of empowerment (5-7). Consistently with this, the fundamental principle of learning is the individual's own experience, and it is especially important that the learner is an active participant and not a passive recipient of information or an outside observer (6, 8). From the point of view of the ideology of empowerment the above-mentioned aims of medicines education appear, for example, as follows:

**A** as required by their individual stage of development children are taught about the correct use of medicines beginning as early as in the primary school; issues are discussed for example about what is good to know about medicines before starting to use them – just warning about medicines is

not enough,

**B** skills associated with the use of medicines are practiced, for example by assessing the prevalence of adverse reactions described in the package leaflet or by reflecting on how to avoid them,

**C** pupils are encouraged to carry out active conversations about medicines with health care professionals, which may for example be practiced through role-playing during medicines education lessons involving a visit to the pharmacy.

On the website, with the help of scheduled lessons, medicines education is structured as an entity with a logical progression. The subjects to be taught are designed in such a way that they support the targets of medicines education as set out in the curriculum. The entities taught to 7<sup>th</sup>–9<sup>th</sup> graders (in accordance with the school system in Finland) are more extensive and provide more in-depth information than those taught to 3<sup>rd</sup>–6<sup>th</sup> graders. In the lower secondary school an additional viewpoint is also offered by the search for information about medicines and by assessment of its reliability. The aim of medicines education targeted at 1<sup>st</sup>–2<sup>nd</sup> graders is to establish a base for the understanding of the correct use of medicines.

The fundamental principles of the curricula require teachers to discuss the correct use of medicines at their lessons (1). The future will show what sort of reception this challenge receives among them and how they will use the website of medicines education in their teaching. The biggest obstacle in putting medicines education into practice may actually be the teachers' own attitudes towards the use of medicines (9).

Medicines education is not the responsibility of teachers alone. The biggest responsibility for teaching the correct use of medicines lies of course with the parents. The parents' own attitudes are also apparent in their actions. Viewpoints strongly against medicines lead to a situation where parents themselves do not wish to use medicines or give them to their child, nor do they wish to discuss them (10-12). To warn the child about medicines may also develop in the child a very reserved attitude towards them (13). It is nevertheless by personal experiences and by our own active conduct that we could promote the process of empowerment (6, 8). It is a very different experience that the child gets of the use of medicines when the mother gives her child a tablet and tells the child to only take one, compared with the situation where the mother explains why the medicine should be taken and perhaps reads the package leaflet together with the child before giving the medicine. Parents can also encourage their child to discuss medicines when meeting a health care professional.

A child learns about medicines, their use and the way in which they are discussed when, for example, attending a doctor's appointment, or visiting a school nurse, a pharmacy or a dentist. A health care professional may, however, find it difficult to talk about the child's disease and its treatment directly with the child at the child's level of development (14-18). We therefore need to be educated about the cognitive development of children and its effects on communication.

The use of medicines is discussed in school at a general level and various issues associated with the correct use are deliberated over. The child's disease and medication are discussed specifically with a health care professional. The parents on their part in their everyday life give their child a model of how to use medicines, a model which the child will use when becoming independent (19-20). It is a question of collaboration between a number of parties, which in its entirety is visible to the child alone. Each party should reflect on the form of its own contribution to the child's education and the way in which it conducts a conversation with the child about medicines and their uses.

If medicines education becomes a part of the health education in schools, children will grow into becoming a more knowledgeable generation of medicine users. They learn to become active participants in discussions, who know what issues are involved in the correct use of medicines. We are still a long way away from changing the strong perceptions of laymen, and we need the input of all parties. While attempting to achieve this, it should be borne in mind that medicines education is not a question where children would be encouraged to use more medicines or use them independently and at an ever younger age. Medicines education is about participation in one's own pharmacotherapy, about asking questions and discussing and about the gradual and well-planned transfer of responsibilities to children while they are growing into becoming future users of medicines.

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## Learning from medication errors

# An overdose of methotrexate in a hospital patient

## Why did a typical error of medication take place in our hospital?

In September 2006, an 86-year-old woman arrived at the hospital on referral owing to dyspnoea. She was found clinically and on MRI to suffer from pulmonary embolism. She was admitted to the hospital for treatment and medication was started. Among the eight medicines which, according to the referral, were to be taken at home there was an ongoing anti-rheumatic medication of 'Trexan 5 mg on Tuesdays (in Finnish *tiistaisin*)' which the audio typist had interpreted as 'Trexan 5 mg in the evening (in Finnish *iltaisin*)'. The medication was recorded in this format in the ward medication list.

The patient initially recovered well from the pulmonary embolism, but over a week after admission to hospital she complained about a sore mouth and her general condition became worse. Infection was suspected, but instead anaemia and neutropaenia were detected. This finding gave an incentive 12 days after admission for reviewing the patient's medication, and it was subsequently detected that methotrexate had been given at a dose of 5 mg every day whereas the administered dose should have been 5 mg once a week.

Despite efforts to treat the patient, she did not recover from the neutropaenia, but died of sepsis after 20 days of hospital treatment. Autopsy showed signs of bone marrow depression and, in addition, pneumonia. The

microscopic studies are not yet completed, but an overdose of methotrexate appears to be the likely cause of death.

### Analysis of the case

Except for rare instances, medicines are administered daily. The once a week administration of methotrexate has consequently caused numerous medication errors. The number is so high that we are well aware of the risk even at our hospital. We are nevertheless faced here with the classic 'Swiss cheese phenomenon', very familiar to quality system experts. When the holes in the slice of cheese land on the same spot after an adequate number of slices, the quality default 'cuts through the whole cheese' and an accident is unavoidable. Within our hospital the course of events can be analysed as follows, with the aid of five 'cheese slices':

1. Our doctor on duty acted very professionally by diagnosing a life threatening pulmonary embolism and introducing immediate appropriate treatment. Among other duties he probably dictated 'Trexan 5 mg on Tuesdays (*tiistaisin*)', but an audio typist at her word processor, tired while performing an evening duty, wrote 'Trexan 5 mg in the evening (*iltaisin*)'. Due to the fact that our hospital emergency room in the evenings is always busy, and due to the

constant complaints about long patient 'turnaround times', the doctor did not check the text he had dictated. It was necessary to admit the ill elderly patient for treatment on the ward without delay. Two processes were thereby set in motion, that of the treatment of the pulmonary embolism and of the medication error.

2. It was necessary to admit the patient to a ward in which there was no experience of methotrexate therapy. The nurse therefore recorded the patient's medication from the newly produced hospital record of internal medicine without noticing anything specific in the dosage of methotrexate.

3. The following morning the ward was actually visited by a locum, because the senior doctor was off duty. All the 20 patients in the ward were unfamiliar to the locum, so his visit to the ward was long and tiresome. He was too exhausted to make a thorough enough check of the medications of patients admitted on the previous evening.

4. The following morning the senior ward doctor considered the recovery from pulmonary embolism to have started well, and he had consequently no reason to review the patient's medication list.

5. Over a week after admission to hospital the patient's recovery stopped, however, and her condition took a downward turn.

A complicating infection was suspected at first, and blood tests, for example, were subsequently taken. This is when, in addition to anaemia, neutropenia was detected and an immediate check of the medicines list revealed that methotrexate therapy had continued for the entire hospitalisation period, i.e. for 12 days, at a dose of 5 mg every day. Unfortunately, the error was detected too late.

### What have we learned from this?

Our doctors on duty, who work under enormous work pressures, have not been required to produce a handwritten list of medications or other therapies, or to confirm their case records by their signature for all patients admitted to hospital. The lack of this requirement may also be defended by the fact that the doctor on duty is responsible for the treatment of admitted patients only 'until the following morning', when the senior ward doctor will examine the patient and prescribe the treatment. In fact, following this procedure there have been no accidents (as far as we know) for at least 5 years. We have now nevertheless altered the procedure. All doctors on duty are required to check any case reports that they dictate.

I would nevertheless like to emphasise one point. For decades we have enjoyed an excellent pharmacotherapy quality system in outpatient care: the dispensing pharmacist has phoned from the pharmacy if there have been anything suspicious about the administration we have prescribed, especially in the case of an excessive dose. Could this medication error have been avoidable if the prescription had been handed out in outpatient care? I am fairly sure it



*A 'safety alert' about incorrect dosage of methotrexate proposed by the UK's National Patient Safety Agency, NPSA. Methotrexate therapy was denominated as a 'high risk treatment process' in the UK in 2004 after 25 mortalities had been reported as a consequence of the treatment.*

would have been. The pharmacy would at least have contacted us, merely because methotrexate should not be administered without intermission for longer than a maximum of five consecutive days. Hospitals should therefore also employ pharmacists or other quality assessors of the drug treatment given. The electronic data systems at our hospital have not yet had integrated into them functions that would alert us and give an advance warning about incorrect doses of medicines (Figure).

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Towards the safer use of oral methotrexate. The National Patient Safety

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## Consumption of conventional antirheumatics in Finland in 2004

About 0.8% of Finns suffer from rheumatoid arthritis (1), while about 1.6% of the population are entitled to special refunds pertaining to rheumatic diseases (2). In 2004 there were 81,527 people in Finland with entitlement to a special refund of the cost of their medicines for disseminated connective tissue diseases, rheumatic arthritis and similar conditions (special refund category 202). About a third of them were men. Of those entitled to refunds, 51,907 were reimbursed for the cost of their conventional antirheumatic agents (3). The average annual costs of antirheumatics amounted to EUR 252 per patient (3).

Great progress has been made in the medical treatment of rheumatoid arthritis in the past couple of decades (4-6). Rheumatic diseases were previously treated with antirheumatics known as conventional antirheumatics, such as sulphasalazine, hydroxychloroquine and corticosteroids (5, 6). Methotrexate has since become the primary medication for active rheumatoid arthritis, both alone and in combination with other drugs (6, 7). The benefits of combination treatments have been recognised in several studies, perhaps resulting consequently in an increase in their use (4, 5, 7). Nowadays medical treatment of rheumatoid arthritis consists of antirheumatic and immunosuppressive drugs and anti-inflammatory analgesics (5, 7) with varied

efficacy depending on the drug and on the individual.

The most recently introduced antirheumatics include biological medicinal products, such as etanercept, infliximab, adalimumab and anakinra (5, 8). Biological medicinal products for the treatment of rheumatic disease are very effective, but they are extremely expensive, and their use is consequently directed towards those who will most benefit from the treatment. In 2004 a total of 1,502 persons received a reimbursement from the Social Insurance Institution for the cost of the biological medicinal products eligible for restricted basic refund (category 313). The average cost per patient was EUR 12,803, and total costs amounted to EUR 19.2 million, i.e. over one and half times as much as when compared with the total costs of conventional antirheumatics (EUR 12.6 million) (3).

The aim of this study was to describe the use of conventional antirheumatics and corticosteroids for the treatment of disseminated connective tissue diseases, rheumatic arthritis and similar conditions. The regional and socio-economic spread of long-term use of prescription drugs for rheumatic diseases in Finland in 2004 was also studied. The study was carried out as a register-based survey of the data of the Social Insurance Institution and Statistics Finland. The study subjects were randomly chosen among

patients entitled to reimbursement of medicine costs under the special refund category 202. Their reimbursed costs of antirheumatics in that refund category were included in the data along with the total annual costs of their other reimbursed medications.

The subjects in the study consisted of 29,433 patients suffering from disseminated connective tissue diseases, rheumatic arthritis and similar conditions, who received a total of 54,544 prescriptions for their antirheumatic agents in 2004. The subjects therefore covered 36% of the individuals with special refund entitlement 202 and 57% of those reimbursed for the cost of their conventional antirheumatic agents in 2004. The proportion of male subjects was 31%.

### Results

In comparison with the total population, the prevalence of disseminated connective tissue diseases, rheumatic arthritis and similar conditions among the subjects was on average higher in women, the elderly, those with a lower level of education, in the Finnish-speaking population, small town residents and residents outside Helsinki and Uusimaa hospital district, than in men, younger patients, those with a higher level of education, those with mother tongues other than Finnish or Swedish, and large town residents. Division by age and sex of

the subjects is presented in Fig. 1.

The 10 most commonly used therapies (62%) are presented in the Table, which incorporates all corticosteroids including both injections and tablets. The drugs most commonly used alone included sulphasalazine, methotrexate and hydroxychloroquine, and the most common combination treatments were methotrexate with prednisolone or methotrexate with sulphasalazine. Sulphasalazine was a distinctly more expensive drug compared with prednisolone, methotrexate and hydroxychloroquine (Table). The combination of azathioprine and methotrexate was the most commonly used in the 0–19-year-old age group, sulphasalazine among the 20–59-year-olds, and systemic corticosteroids in the over 59-year-olds.

During the year the study subjects were each on average using two antirheumatic agents. The number of conventional antirheumatics and corticosteroids in relation to the year of introduction of the special refund entitlement is presented in Fig. 2. That Figure shows that those who had recently received their special refund entitlement were on average given a multi-medication treatment more often than those who had been ill for a longer period of time. This reflects fairly accurately the Current Care guidelines which suggests that a recently acquired rheumatoid arthritis be treated by administering a combination therapy (7). A total of 15,447 (52%) of the subjects used systemic corticosteroids, and of these 443 used more than one corticosteroid during the year. The use of corticosteroids was more common in the long-term sufferers (Fig. 2).

The costs of conventional antirheumatics in the data were

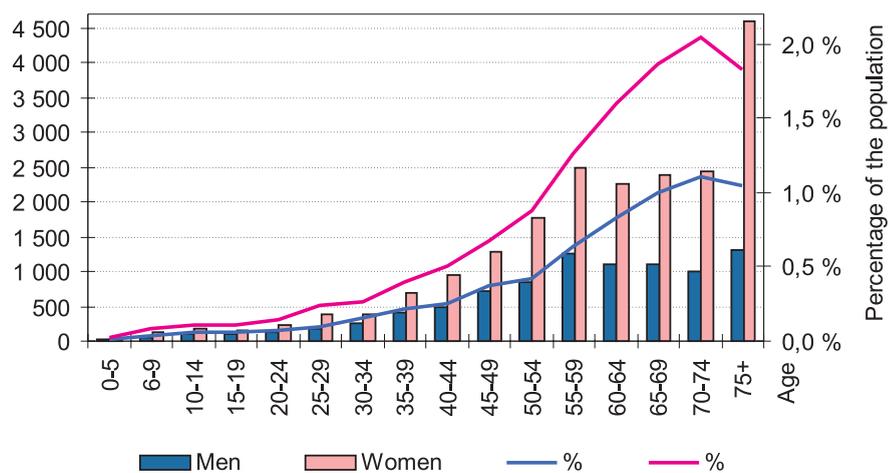


Fig. 1. Division by age and sex, and percentage of the corresponding population group.

The most commonly used monotherapies and combination treatments using conventional antirheumatics and systemic corticosteroids.

Medication	Number of users	Average cost, €/person/year
1. Systemically used corticosteroids (H02AB)	4,380	49
2. Sulphasalazine (A07EC01)	3,432	193
3. Oral methotrexate (L04AX03)	2,266	55
4. Systemically used corticosteroids and oral methotrexate	1,883	85
5. Hydroxychloroquine (P01BA02)	1,559	56
6. Sulphasalazine and systemically used corticosteroids	1,100	237
7. Sulphasalazine and oral methotrexate	996	260
8. Systemically used corticosteroids and hydroxychloroquine	996	85
9. Systemically used corticosteroids, oral methotrexate and hydroxychloroquine	827	151
10. Oral methotrexate and hydroxychloroquine	813	120

about EUR 242 (median of EUR 119); EUR 264 for men (median of EUR 135), and EUR 233 for women (median of EUR 111). The costs were highest in the age group of about 20 to 34-year-olds and lowest in the over 75-year-olds. Overall, the medicine costs reimbursed by the Social Insurance Institution in 2004 and represented in the data totalled EUR 1,364 on average (median of EUR 663, range between EUR 3.36 and EUR 48,291).

## Conclusions

A more recently acquired rheumatism was on average treated with a greater number of drugs and more rarely with systemic corticosteroids. The most common antirheumatics used either alone or in combination included sulphasalazine, prednisolone, methotrexate and hydroxychloroquine. The annual costs of conventional antirheumatics were on average EUR 242 per person.

Even though the proportion of patients using new biological medicinal products among those suffering from rheumatism was only a couple of percentages, the costs of biological medicinal products already account for a major part of the total cost of the medicines used in the treatment of rheumatism. It would therefore be appropriate to study the distribution of these high costs and exceptionally costly treatments among the various parts of the country and by age and socio-economic group.

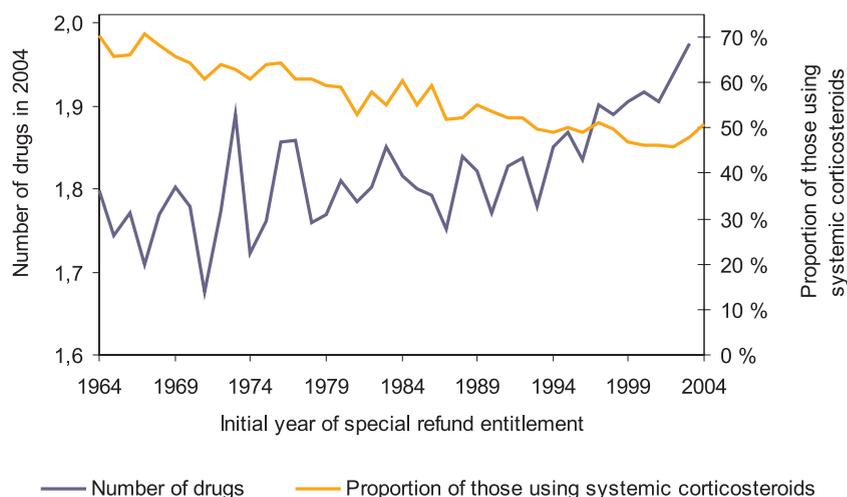


Fig. 2. The average number of conventional antirheumatics and the proportion of systemic corticosteroid use in relation to the start of special refund entitlement.

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# Recommendation for quality criteria for sales promotions of medicines

The work of pharmaceutical sales representatives is marketing, which is aimed at promoting the use of medicines. A sales promotion event at its best provides up-to-date and good quality information about medicines and their use to practising doctors and pharmacists.

In line with the rest of the pharmaceutical marketing, the National Agency for Medicines (NAM) in Finland also monitors compliance with all parts of the pharmaceutical legislation at sales promotions. NAM has established quality criteria for these sales promotion events based on the points in the Medicines Act and Decree important with respect to the communication of appropriate information about medicines which promotes their correct and safe use.

The quality criteria comprise a recommendation which NAM hopes that the pharmaceutical companies will follow in their marketing. To the professional attending a sales promotion event the recommendation will give a perception of what can be expected of the information content of the presentation. Throughout the current year NAM will monitor the extent to which the criteria are followed at these events.

1. A sales promotion representative should have appropriate training (e.g. 'RLE' - registered pharmaceutical sales representative). The education should provide basic information which will be sufficient to enable the representative to give information about the medicine which is as comprehensive as possible.
2. Participants in sales promotion events should be given the current SPC (Summary of Product Characteristics) of the medicinal product. Information about the legal prescription and legal terms of supply of the medicine, including details of price and reimbursement, should also be available to the participants in the event. In addition to unit prices, price comparisons should also address the total costs of drug treatment.
3. Information given about the medicinal product should in all its details correspond to the information contained in the SPC. Research results used in the sales promotion events which are not included in the SPC should correspond with or support the information in the SPC.
4. The focus of the presentation may only be on a therapeutic indication approved for the medicinal product. Presentation of the use of the medicine for any other therapeutic indication is prohibited, even if it has had proven scientific evidence, or another indication has been approved in another country, or planning of an extension of the indication in the SPC is under way, or an application for an extension has been filed. In addition to the therapeutic indication, the presentation should address any other recommendations that exist for the use of the medicine.
5. The source of the information used at the presentation should be given accurately, and any publications and previously unpublished references should be made available to the participants in the sales promotion event.
6. Any quotations, figures and tables extracted from the literature or research material should be accurately presented in accordance with the original source. Different research results may not be combined, for example for the purpose of comparison of medicinal products.
7. Adverse reactions, interactions and contraindications and other issues involved in the safe use of the medicinal product should be stated with sufficient clarity.
8. Any material used at the sales promotion event should convey faithfully the medical importance of the product as a whole in relation to other treatment options.
9. A sales promotion of medicine is aimed and targeted only at individuals authorised to prescribe and dispense the medicinal product.
10. The presentation should focus on information relating to the medicinal product. Any hospitality offered in conjunction with the sales promotion event should be moderate.

*Tiina Kostiainen*