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Hannes Wahlroos DIRECTOR GENERAL National Agency for Medicines

National Agency for Medicines' 10th Anniversary

The National Agency for Medicines will turn ten years at the end of February. Looking back, our first decade has passed quickly in view of the enormous challenges we faced in the spring of 1993. In this regard the life of an organisation resembles that of an individual. Ahead of us looms the great unknown, but every-day life and its experiences is fast behind us.

It is important that a sense of realism is present in the life of organisations. Ten years of medicines' and medical devices' control is merely 1/34 of the total period of such control in this country. The founding of *Collegium Medicum* in Stockholm in 1663, all of 340 years ago, can be taken as the starting point. Of course, the subject matter of medicines control then is hardly comparable with that of today.

Has NAM lived up to the expectations leading to its foundation? I am not competent to answer that question, it should rather be put to our clients (refer TABU 6/2002, page 3) and our 'owners', i.e. the Ministry of Social Affairs and Health, playing the role of parent company governing our business sector.

Whatever mark NAM gets for its performance, two facts should be borne in mind: We should learn from the past and face the future without prejudice. I am referring to strategies, challenges, daring to embark on innovations, and questioning the past. In this regard, the dynamic medicines' and medical devices' industry will not leave anyone cold. Smaller and bigger changes are always happening, both at home and in the European Union.

Pharmaceutical services in Finland have recently undergone surprisingly extensive and rapid changes. Generic substitution is the best example of that trend. I consider it to be the most significant pharmaceutical policy reform in Finland in many decades. Now we must ensure that this positive reform is properly implemented in practice. Patients, consumers and health care professionals will evaluate the reform on the basis of their own experiences. Our task at NAM is to draw up a list of exchangeable medicinal products, to maintain it up to date, and to publish it.

Another sudden change was seen in the week preceding Christmas, when the Government decided to pass a decree allowing pharmacies to give discounts to their regular customers. This would not be remarkable if our Parliament had not expressly clarified the Medicines Act last summer, as far as unified pricing of medicines was concerned. It is easy to predict that the operating principles of pharmacies as producers of equal, basic pharmaceutical services for all will still have to be reviewed.

Major reforms of the control of medicinal products and medical devices within the EU are still pending. Together with the effect of the enlargement of the EU, such reforms will have an effect on NAM's operating environment. In order for NAM to be able to serve Finnish interests in promoting the safety of medicines and medical devices, it should be able to wield more influence there, where major decisions are made. It is a question of greater engagement in co-operation in the European environment. NAM is well equipped to succeed in that, thanks to the experience and know-how accumulated during a decade of activity. Ongoing improvements in operations, a new organisation, and taking care of our resources, boost our faith in our future success.

I should like to thank the customers, associates, interest groups and collaborators of the National Agency for Medicines for the smooth co-operation and constructive feedback during our first 10 years. I should also like to thank the readers of TABU for their interest in drug information. I take this opportunity to publicly thank the professional, highly professional and motivated staff of National Agency for Medicines.

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The treatment of gout

The diseases gout, calcium pyrophosphate arthropathy (pseudogout) and hydroxyappatitis are all classed as crystal-induced arthritides. The most commonly occurring one in practice is gout. An acute attack of gout results from the deposition of urate crystals in the joint. If the methods of treatment are chosen correctly the patient will recover and remain symptom-free, and it is this, which makes the diagnosis of gout, and distinguishing it from other forms of arthritis, especially important. The treatment of the acute stages of gout focuses on relieving the symptoms of the arthritis. The primary treatment of hyperuricaemia is diet, but the treatment of gout often also requires medical treatment to reduce the level of uric acid.

The aetiology and pathogenesis of gout are influenced by both hereditary and environmental factors. Chronic hyperuricaemia is characteristic of the disease (in men, plasma urate > 420 micromol/l, in women > 340 micromol/l). Recurrent gout attacks are due to further depositions of urate crystals in the joint.

Urate is formed as an end product of purine metabolism in the body. Humans receive about a third of their daily purine supply from food, two thirds being formed endogenously. In the majority of primary gout sufferers, hyperuricaemia is caused by a reduction in the urate excretion via the kidneys in proportion to the serum urate level. In about 10% of patients, hyperuricaemia is caused by excessive endogenous production of urate (1). The underlying factors causing increased urate production may include certain rare genetic enzyme deficiencies, increased cell turnover (myelo- and lymphoproliferative diseases and haemolytic conditions), increased purine catabolism or increased dietary intake of purines. About two thirds of the urate is excreted via the kidneys. Uric acid excretion is reduced by, for instance, renal insufficiency, acidosis, fasting and fluid deficiency, hypertension, hyperparathyroidism and hypothyroidism among the endocrinopathies, alcohol, lead, and among drugs especially by diuretics, ethambutol, pyrazinamide, levodopa, beta-blockers and low dose salicylate (2), and by ciclosporine (3).

There are good grounds for considering gout as part of a metabolic syndrome, the typical features of which include an excessive amount of calories in the diet, overweight, excessive use of alcohol, dyslipidaemia and insulin resistance (4,5).

In the majority of patients, gout sets in first as an acute inflammation of the metatarsophalangeal joint of the great toe (podagra), but in about a fifth of the patients the disease begins polyarticularly. An acute attack of gout often occurs at night, when the reduced temperature promotes the circumstances under which the precipitation of urate crystals occurs. After an acute attack of gout, arthritis generally subsides within a couple of weeks. If hyperuricaemia is not corrected by change of life style and/or medication, the attacks will recur and the patient will exhibit tophi, that is, subcutaneous accumulations of deposited urate (6).

The diagnosis of gout is based on the clinical picture of the disease, on hyperuricaemia and, above all, on the detection of urate crystals in the synovial fluid, or of tophi (7). Even though hyperuricaemia is found in almost all gouty patients, its differential diagnostic value is minimal. Hyperuricaemia occurs in the general population more frequently than gout does. As the serum urate level arises, however, the risk of an acute attack of gout increases (8, Table 1). Radiological changes typical of gout are not detected in the joints until the patient has suffered from the disease for several years.

The treatment of gout is aimed at focussing effectively on the risk factors of the disease. The importance of restricting the intake of purines, proteins and alcohol has traditionally been emphasised in dietary advice (6, Table 2). The significance of weight loss has also been emphasised in recent years, especially where there is an associated metabolic syndrome (1). Even on a strict diet, the urate concentration is usually only reduced by 100–200 micromol/l. Asymptomatic hyperuricaemia is not treated as a rule, but if the urate level is very high (plasma urate > 600–700 micromol/l) medical treatment may be indicated. With co-existent myelo- and lymphoprolipherative malignancies, it is necessary also to treat asymptomatic hyperuricaemia (9).

Drugs whose mechanisms of effect vary greatly have been used in medical treatment of gout. Their effect is based on

- the reduction of urate production by xanthine oxidase inhibition (allopurinol)
- the increase of urate excretion at the renal level (uricosuric drugs)
- urate oxidation (rasburicase)
- the alleviation of symptoms of acute gouty attacks (colchicine, NSAID)

Allopurinol

Allopurinol exerts a competitive inhibitory effect on the enzyme xanthine oxidase and thereby reduces the urate production in the body. Allipurinol has an active metabolite which is excreted in the urine, allowing once daily administration of the drug, but the dose should be decreased with co-existing renal insufficiency (9).

Unlike uricosuric drugs, allopurinol decreases the excretion of uric acid while correspondingly increasing the urine hypoxanthine and xanthine concentrations.

Rapid changes in plasma urate concentrations may cause a tendency to gouty attacks, but allopurinol therapy will not lead to the formation of urate crystals or stones in the urinary tract. Allopurinol is therefore the drug of primary choice, especially when the patient is found to have urate stones in the urinary tract, the urate excretion is abundant, or the clinical picture is otherwise complicated. The effect of allopurinol is also partly based on the reduction in purine synthesis in the body. A small initial dose will reduce the risk of an acute gouty attack at the beginning of treatment.

Adverse reactions

The estimated incidence of adverse reactions of allopurinol reported in the literature varies greatly among the different reports (between 5%

Table 1. Incidence of gout and plasma urate level (8)

Incidence (1/1,000 inh/day) 0.8 0.9 4.1	Plasma urate μmol/l) < 420 420–470 480–530
4.1	480–530
49	> 540

Table 2. Diet for gouty patients

Very high contents of purines, to be to- tally avoided Organ meats
Small fish, shellfish Yeast
High contents of purines, to be eaten in small amounts only Fish
Meat
Beans, peas, asparagus, mushrooms
Low contents of purines, can be eaten
liberally
Cereal products
Milk products
Eggs, fat, sugar (Note: weight loss!) Fruit
Potatoes, most vegetables
Coffee, tea, cocoa, spices Fish roe
Other agents with an adverse reaction Alcohol, especially beer

Table 3. Adverse reactions caused by allopurinol reported to the National Agency for Medicines in Finland during 1973–2002*

65 reports in total

Acetylsalicylic acid

The most common reactions Skin reactions Elevated hepatic enzymes Cytopaenia	
Agranulocytosis	13
Rare Stevens-Johnson syndrome	2
Fatal Aplastic anaemia Agranulocytosis and sepsis Thrombocytopenia	

* The information obtained from the ADR register of the National Agency for Medicines cannot be considered complete in quantity or quality. and 25%). The most common ones include mild symptoms of GI tract irritation, which can be alleviated by taking the drug at mealtimes. The most dreaded symptoms, albeit rare, are hypersensitivity reactions (varying from mild rash to life-threatening toxic epidermal necrolysis; Lyell's syndrome). Other hypersensitivity reactions include fever, eosinophilia, elevated hepatic enzymes, acute interstitial nephritis and exacerbation of renal insufficiency (10). It has also been suggested that hypersensitivity occurs three times more often in patients with renal insufficiency than in other patients (2). Haematological adverse reactions include leukopaenia, neutropaenia and aplastic anaemia. Agranulocytosis is a rare and severe adverse reaction of the treatment. Patients on cytostatic therapy, in particular, are exposed to bone-marrow damage.

A total of 65 adverse reactions where the suspected primary cause was allopurinol therapy were reported to the National Agency for Medicines in Finland during 1973–2002 (11, Table 3). The most common adverse reactions were skin reactions. elevated hepatic enzymes and cytopaenia. Two patients were reported as having the rare Stevens-Johnson syndrome. Agranulocytosis had occurred in 13 patients. In seven fatal cases the adverse reaction was haematological, mainly bone-marrow damage and associated occurrence of cytopaenia.

The oxidation-inhibiting effect of allopurinol, mercaptopurine and azathioprine deserve particular attention among interactions. The efficacy and toxicity of these drugs are significantly increased in concurrent therapy, and the dose is therefore reduced to 25% of the normal dose. Concurrent ampicillin therapy causes a threefold increase in the risk of skin rash. Allopurinol potentiates the toxic effects of cyclophosphamide.

Probenecid

The effect of probenecid is based on urate reabsorption inhibition in the renal tubulae, thereby increasing the uric acid excretion. Abundant fluid supply and diuresis must be ensured during treatment. Urate easily becomes precipitated in acid conditions; to prevent the development of kidney stones, urine is alkalised by giving the patient sodium bicarbonate (3–6 g per day). Probenecid is generally well tolerated; the most common adverse reaction is mild nausea. Rare adverse reactions have included rash, a rise in temperature and nephrotic syndrome (10). An interaction which deserves attention is the inhibiting effect that probenecid has on the tubular excretion of certain drugs, the most important drugs being furosemide, methotrexate, nitrofurantoin, zidovudine and several anti-inflammatories. Probenecid prevents paracetamol conjugation with glucuronic acid and diminishes its clearance by half. It is recommended that the dose of paracetamol be halved when used together with probenecid. Probenecid also inhibits zidovudine glucuronidation and increases the drug plasma concentration; in concurrent use the dose of zidovudine should therefore also be halved.

Sulphinpyrazone

This drug increases renal excretion of urate and also has a potent antithrombotic effect. Its effect in patients with renal insufficiency may be better than that of probenecid. Reports of adverse reactions have included lack of appetite, nausea, vomiting and abdominal pains. Rare adverse reactions have included bone-marrow damage and skin rash (9,10).

Urate oxidase

By using combination-DNA technology, a urate oxidase, rasburicase, has recently been developed for the prophylaxis and treatment of hyperuricaemia associated with haematological malignancies. The drug is strongly uricolytic and the onset of effect is considerably faster than that of allopurinol (12). Rasburicase has so far only been indicated for use at the start of chemotherapy for malignant blood diseases.

Treatment of acute gout

The treatment of acute gouty attacks consists of rest, topical cryotherapy and effective anti-inflammatory therapy. A glucocorticoid injection can be administered into the joint in conjunction with diagnostic joint puncture and synovial fluid aspiration; this usually abates inflammation of the joint very effectively.

Colchicine

The effect of colchicine is based on the inhibition of the leucocyte-mediated inflammatory process associated with acute crystal arthritis. The drug also has an antimitotic effect. Colchicine has a potent effect in attenuating acute gouty attacks, but its use is restricted by uncomfortable GI tract complications, mainly diarrhoea. Intravascular administration is also a possibility.

Conclusion

Hyperuricaemia is also extremely common in the Finnish population. As overweight and other metabolic syndromes become more frequent in the population, symptom-free hyperuricaemia forms part of an accumulation including several other risk factors in these patients. Change of life style and dieting have a beneficial effect on hyperuricaemia as well as on other risk factors. Asymptomatic hyperuricaemia is not generally treated with drugs. In the treatment of gout both diet and medication aim at reducing the urate level and by doing so also reducing the risk of recurrent gouty attacks.

Literature

1. Fam AG. Gout, diet, and the insulin resistance syndrome. J Rheumatol 2002;29:1350-5.

 Emmerson BT. The management of gout. In: Klippel JH, Dieppe PA, eds. Rheumatology, Second edition. London: Mosby International 1998;8:15.1.-8.
Pascual E. Gout update: from lab to the clinic and back. Curr Opin Rheumatol 2000; 12:213-8.

4. Dessein PH, Shipton EA, Stanwix AE, Joffe BI, Ramokgadi J. Beneficial effects of weight loss associated with moderate calorie/carbohydrate restriction, and increased proportional intake of protein and unsaturated fat on serum urate and lipoprotein levels in gout: a pilot study. Ann Rheum Dis 2000;59:539-43. 5. Lin KC, Lin HY, Chou P. The interaction between uric acid level and other risk factors on the development of gout among asymptomatic hyperuricemic men in a prospective study. J Rheumatol 2000;27:1501-5.

6. Isomäki H. Kihti. Duodecim 2001;117:1843-7.

7. Swan A, Amer H, Dieppe P. The value of synovial fluid assays in the diagnosis of ioint disease: a literature survey. Ann Rheum Dis 2002; 61:493-8. 8. Campion EW, Glynn RJ, DeLabry LO. Asymptomatic hyperuricemia. Risks and consequences in the Normative Aging Study. Am J Med 1987:82:421-6. 9. Brooks PM. Rheumatic disorders. In: Trevor, Speight & Nicholas, Holford, eds. Avery's drug treatment, Fourth edition. Adis International Ltd. 1997:1149-53. 10. Biscarini L. Drugs used in gout. In: Dukes MNG, Aronson JK, eds. Meyler's side effects of drugs, 14th edition. Elsevier Science B.V. 2000:310-4.

11. The ADR register of The NAM, Finland.

12. Pui CH, Mahmoud HH, Wiley JM, ym. Recombinant urate oxidase for prophylaxis or treatment of hyperuricemia in patients with leukemia or lymphoma. J Clin Oncol 2001;19:697-704.

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Misuse of CNS drugs

The use of CNS drugs for non-medical purposes is a problem in many countries. The problem occurs in Finland as an associated use of narcotics and drugs. There are various ways of acquiring drugs for misuse. Compared with the previous year, the number of break-ins and thefts in pharmacies and other units increased last year. The number of forged prescriptions is also suspected to have increased in recent years. Illegal importations of drugs prone to misuse have also caused problems. A proportion of the drugs which end up by being misused is acquired by illegal means, but the legal drug distribution methods also serve as a channel for misuse, and a proportion of legally acquired drugs ends up being misused and sold on the street. The proportion of CNS drugs legally prescribed by physicians and ending up in illegal use is unknown, as also is the size of the patient group sustaining these operations. In order to establish the extent of the problem and the necessary measures required, a study of the prescription and non-medical use of CNS drugs has been carried out by a working group set up by the National Board of Medicolegal Affairs.

The starting point of the study

No national register in Finland is maintained with respect to the dispensing of CNS drugs. As the information on all the prescriptions and supplies of CNS drugs is only registered individually by each pharmacy, the information has had to be collected in the form of prescription samples from pharmacies. The study comprised information from 275 pharmacies in the hospital districts of Helsinki and Uusimaa, Keski-Suomi and Varsinais-Suomi covering the CNS drugs supplied during the period between 1.5.2001 and 15.6.2001. A total of 170,499 CNS drug prescriptions were received, by which drugs were supplied to 110,524 different individuals.

It is difficult to establish the proportion of drugs ending up in nonmedical use on the basis of the information concerning the prescription and supplying of CNS drugs. The study had established certain criteria which, when transgressed, indicated that the individual in question belonged to a group at risk of non-medical use. The condition was that the individual had during the study period either received five or more CNS drug supplies which had provided him or her with a total of a minimum of 300 units of a CNS drug, or that the amount of a CNS drug received by the individual was a minimum of 500 units, or that the patient had received a minimum of 1,500 ml of a cough preparation containing codeine. It is understood that the risk group defined in the study consists not only of problem users of drugs or narcotics but also of other individuals, such as patients with cancer and pain, and of misusers on appropriate replacement and/or withdrawal therapy. The study is the first of its kind and it reveals the extent of the problem of legally prescribed CNS drugs ending up for misuse in Finland.

Results

According to the criteria chosen for this study, the proportion in the group at risk of non-medical use was 2.4% of all patients, but they were supplied with 9.7% of all CNS drug prescriptions received and 12.9% of the total amount of the CNS drugs. A proportionate comparison of the population of the three hospital districts under study with the entire population of Finland enables the researchers to estimate that the group at risk of nonmedical use comprises about 6,600 individuals in the entire country. This group gets into its possession about 13% of all CNS drugs prescribed by physicians. A comparison with all patients showed that the conspicuous proportions in the risk group were of male patients in the age groups of 15-24 years and 25-39 years, and female patients in the age group of 40-54 years.

The prescription and supply of CNS drugs to the group at risk of non-medical use differ in many ways from other prescription and supply practices in the overall study material. It is characteristic of this group that the CNS drugs are acquired from several different physicians and from several different pharmacies. Over 60% of the individuals in the risk group were supplied with CNS drugs prescribed by more than one physician during the six-week period under review. According to the study, this group was supplied with bigger amounts and more often than total patient group with several concurrent sedatives, analgesics containing codeine and hypnotics with long-term effect.

The risk group also received midazolam and temazepam more frequently than others. The suspicion of possible misuse of a cough preparation containing codeine was focused on a couple of individual patients. The package sizes and drug quantities prescribed also differed between the groups. According to the study, the group at risk of nonmedical use was on average prescribed larger packet sizes of CNS drugs and higher quantities than the overall group studied. The highest total quantities prescribed by different physicians and supplied to a single patient amounted to about 40 tablets of opioids and about 60 tablets of hypnotics per day.

Surprisingly, the study revealed that sickness insurance benefit was paid out for drugs supplied to the group at risk of misuse almost as often as for the CNS drugs supplied to the entire group.

The study material showed that the majority of CNS drugs for the group at risk of non-medical use were prescribed by non-specialists (61% of the prescriptions); 23% by other than psychiatrists and 14% by psychiatrists. Interns and dentists wrote a couple of percent of the CNS drug prescriptions. There is hardly any difference in this distribution in the study material overall. The study also discussed the significance of the years of service of the prescribing physicians in the prescribing of CNS drugs. A proportionately larger quantity (12%) of the CNS prescriptions written by physicians with a greater number of

years of service were supplied to the risk group for non-medical use than by physicians with fewer years of service (9%). "Middle-aged" physicians, by their years of service, were placed between these two groups. The study did not go into details about the physicians' offices, i.e. whether they fell within the public or the private sector. The study results show that the majority of CNS drugs are prescribed and supplied for the purpose of medically justified and appropriate treatment. The study nevertheless confirmed unequivocally that obtaining drugs for misuse by deceiving the physicians, and picking them up from several different pharmacies, is easy.

Proposals of the Finnish Working Group for the measures by which it would be possible to prevent CNS drugs from being acquired for misuse and street sales.

- It would be important to establish and review the exchange of information between the physician and the pharmacy in order to prevent the above problem. This could be arranged primarily with the patient's consent.
- It should be possible to increase the exchange of information even without the patient's consent where the physician or the pharmacy has a strong reason to suspect misuse. When drugs are collected from the pharmacy for misuse or for selling on the street, it is justified to doubt whether it is any longer a question of relationship to treatment and whether the protection of privacy continues to serve the needs of the patient. In situations where suspicion of misuse is justified, the physicians and the pharmacies should by law be provided with the opportunity to obtain details of the drugs supplied to the individual in question.
- Since the study showed that sickness insurance benefit was paid to patients of the group at risk of missuse as frequently as to other groups of patients, the benefits of the information collected thereby should be made more readily available. Finnish regulations about secrecy ought not to prevent the Social Insurance Institution from being able to provide details of drug purchases to the prescribing physician, if the insured individual, despite a warning, continues to buy more drugs than necessary for the treatment of his or her ailment. By increasingly using the benefit of this procedure, the physicians could obtain information about patients whose prescriptions end up being used for anything else but treating their illnesses.
- The number of forged prescriptions and false information given in computed prescriptions has increased in recent years. Pharmacies should focus increasingly on confirming the accuracy and genuineness of prescriptions when dealing with CNS drugs. In unclear situations the information should always be checked with the physician. Physicians can also prevent prescription forgeries by reviewing their prescription practices. Clear, legible notes and a proper signature – not merely initials or a cross – and the use of a stamp will make forgery more difficult and increase the possibility of detection of forgeries and other incongruities at the pharmacy.
- Due to forgeries occurring, telephoned prescriptions of CNS drugs should, for example, be restricted to the smallest package size. When the regulation on drug prescriptions comes to be renewed, the complexities associated with CNS drugs established by this study should be taken into account. Issuing a treatment recommendation for CNS drug prescriptions and therapeutic use would also be advantageous at the present time.

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Consumption of OTC drugs in Finland during 1996–2001

These consumption data are based on the sales statistics for drugs compiled by the National Agency for Medicines from the drug sales of wholesalers to pharmacies. As Finnish pharmacies have a fast turnover of stocks (1), the sales figures of wholesalers can be assumed to reveal which OTC drugs the consumers buy from pharmacies. The sales of OTC drugs for outpatient use by pharmacies are reviewed in a style similar to that of Finnish Statistics on Medicines (2). The drugs are listed according to ATC Codes (Table). The group of preparations used for common 'flu-like symptoms contains cough, cold and throat preparations. The cold preparations include combination preparations indicated for the treatment of common 'flu-like symptoms and they contain e.g. acetylsalicylic acid or opium alkaloids or their derivatives. The group titled "Other" is the largest and most varied one, containing, for instance, several topical preparations and eye and ear drops also available as OTC drugs.

The defined daily doses (DDD/1,000 inhab. /day) are used as a means of calculation to assess the consumption of OTC drugs (Fig. 1). Not all drugs, however, can be assigned a DDD, owing to the variation in the doses used, e.g. dermatological preparations, vitamins and minerals. In these instances, a second means of calculation used is the cost (retail prices in Euros) (Fig. 2). On examining the figures it must be borne in mind nevertheless that the amount of the cost varies according to the health care price index (2).

Development of sales

The sales of prescription and OTC drugs by pharmacies in Finland in 2001 based on retail prices totalled EUR 1,587 million. The proportion of OTC preparations came to about EUR 251 million, i.e. 15.8%. In 1996, the sales of drugs in outpatient care amounted to EUR 1,110 million, of which the OTC drug proportion was about EUR 226 million (20.4%). The sales of OTC drugs by pharmacies have consequently increased to some extent, but their share of the total sales has shrunk (2).

The sales of OTC drugs were at their lowest in 1998. Since then, the sales increased and have grown by 3-6.5%.

Drugs for GI disorders

Drugs for GI disorders were, as defined daily doses, the biggest group of OTC drugs used in 1996–2001 (Fig. 1). Their use continued to grow somewhat at the start of the century. The OTC consumption of these drugs in 2001 mounted to 36.6 DDD/1,000 inh./day (Fig. 1). This amount was divided between the consumption of laxatives, 75%, antacids and H₂-receptor blockers 15%, and the rest, antidiarrhoeals, digestives and antiflatulents, 10% (2).

Measured by cost, the drug group for GI disorders remained in third or fourth place over an entire period of six years (Fig. 2). The most commonly used drugs, laxatives, are relatively cheap.

Analgesics

Analgesics had the second highest OTC consumption figures, measured as DDD, in 1996–2001 (Fig. 1). In 2001 the consumption reached 26.9 DDD/1,000 inhab./day (2).

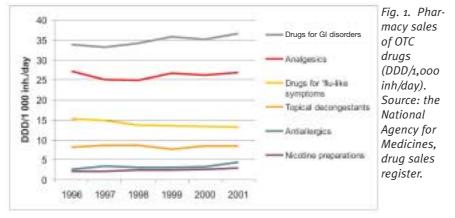
Combination analgesics are being replaced by the use of preparations containing only a single medicinal substance (3). In 1996-2001 the highest increase in OTC consumption was of ibuprofen (2). The consumption of paracetamol has increased only slightly, whereas the consumption of acetylsalicylic acid and that of ketoprofen have diminished (2). Analysis of consumption shows that changing the prescription status of analgesics from POM to OTC appears to decrease the prescription sales of the drug temporarily without necessarily increasing its OTC consumption (3).

In money terms, the analgesics group has shown the highest OTC sales figures ever since 1997 (Fig. 2). The sales of analgesics increased by about 14% during the review period. In 2001, they were bought for self-treatment purposes at a total cost of over EUR 51 million, which is about a fifth of all OTC sales (2).

Drugs for common 'flu-like symptoms and topical decongestants

The third biggest OTC consumption occurred in the group of drugs used to treat common 'flu-like symptoms (Fig. 1). The OTC consumption of cough preparations in 2001 amount-

OTC groups	ATC-code
ore groups	ATC-COUE
Analgesics	
Drugs containing one medicinal substance	
- ibuprofen	Mo1AE01
- paracetamol	No2BE01
- acetylsalicylic acid	No2BA01
- ketoprofen	Mo1AE03
Combination preparations	
- acetylsalicylic compounds	No2BA51
- compounds of paracetamol	No2BE51
- compounds of phenazone (until 1998)	No2BB51
Vitamins and minerals	
Vitamins	A11
Iron preparations	ВозА
Calcium preparations	A12A
Drugs for GI disorders	
Laxatives	A06
Antacids, sucralfate and H2 receptorblockers	A02
Antidiarrhoeals	A07
Digestives, including enzymes	A09
Antiflatulents	Ao2D, Ao3AX
Drugs for 'flu-like symptoms	
Cough preparations	
Expectorants	Ro5C
Cough suppressants	Ro5D
Compounds of cough suppressants and expectorants	Ro5F
Cold preparations	
Throat preparations	Ro2
Dermatologicals	
Corticosteroids used for skin treatment	D07
Topical antifungals	DojA
Antivirals	Do6B
Topical antibiotics	Do6A
Anti-acne preparations	D10
Other	
Nicotine (including chewing-gums, patches etc.)	No7BA01
Antiallergics	
Cetirizine	Ro6AEo7
Loratadine	Ro6AX13
Sodium cromoglicate	So1GX01, R01AC01
Acrivastine	Ro6AX18
Beclomethasone	Ro1ADo1
Levocabastine	Ro1ACo2
Topical preparations for joint and muscular pain	Mo2A
Topical decongestants	Ro1A
Other	



ed to 7.2 DDD/1,000 inh./day (2); 43% of these were expectorants, 36% were cough suppressants and 21% were combinations of these. Expectorants were thus used most of all, even though doubts have been expressed about whether their use for self-treatment is necessary. Preparations containing bromhexin were purchased most of all (44% of the total consumption of expectorants). Over a third (33%) of all expectorants purchased in 2001 were older preparations of guaiphenesin and combination preparations. The proportion of expectorants containing carbocisteine or acetylcysteine was 23%.

The consumption and sales of throat preparations have also been steady. The use of throat tablets containing antiseptics (dichlorobenzyl alcohol and chlorhexidine) was about as great as that of preparations containing antibiotics (gramicidin). Last year, 53% of the throat preparations used were drugs containing antiseptics and 45% of them contained antibiotics.

Topical decongestants were the fourth largest group of drugs used (sympathomimetics, antiallergic agents and corticosteroids) (Fig. 1). The OTC consumption has remained steady for the past few years and totalled 8.4 DDD/1,000 inh./day in 2001 (2). The total cost of topical decongestants purchased last year was about EUR 5.4 million, whereas the sales of cough preparations reached well over EUR 13 million (2).

Antiallergic agents

The OTC consumption of antiallergic agents has also been steady and reached 4.3 DDD/1,000 inh./day in 2001. For the past few years the consumption has somewhat increased, as the more recent, socalled third generation antihistamines became OTC drugs. The consumption in 2001 was, in fact, almost double that of 1996. Year 2001, the consumption of systemic antihistamines sold as prescription drugs in outpatient care totalled 19.3 DDD/1,000 inhab./day; their OTC consumption was 2.9 DDD/1,000 inhab./day. Approximately 15% of systemic antihista-

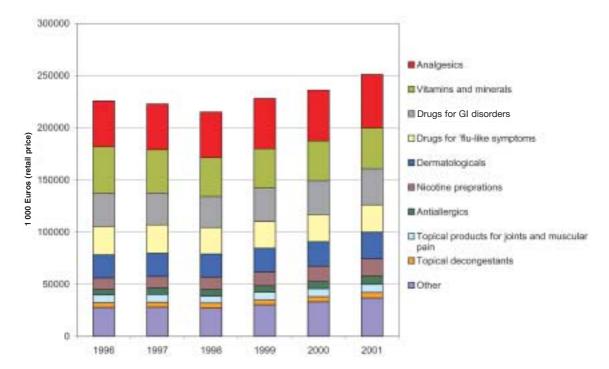


Fig. 1. Pharmacy sales of OTC drugs (in Euros). Source: the National Agency for Medicines, drug sales register.

mines used in outpatient care are indeed bought over the counter. The antiallergic agent reaching the highest OTC sales figures during 1996–2001 was cetirizine (2).

Nicotine

Nicotine preparations used as antismoking agents have also been sold very steadily (Fig. 1). Year 2001 their sales reached over EUR 16 million, giving the group the sixth highest position in drug sales overall (Fig. 2). The sales have increased by 33% since 1996. 86% of the nicotine preparations sold were chewinggums.

Vitamins and minerals

In money terms, the majority of OTC sales in 1996 were of vitamins and minerals (Fig. 2). OTC sales of these preparations have since decreased by 13%. On one hand, the consumption may have been influenced by studies published in the mid 1990s where risks associated with vitamin supplements were discussed (4). On the other hand, the decrease in OTC sales does not necessarily reveal a reduction in their use, since preparations similar to vitamins and minerals may also be purchased from health food shops.

Drugs of this group were pur-

chased to the value of EUR 39 million in 2001, which makes the group the second largest, immediately after the group of analgesics (Fig. 2).

Dermatologicals and topical drugs for joint and muscular pain

The consumption of dermatologicals has remained very steady and has been the fifth largest group in money terms during 1996–2001 (Fig. 2). The majority of OTC preparations sold were topical corticosteroids. In 2001 their OTC sales in outpatient care at retail prices reached over EUR 8 million.

Topical preparations for joint and muscular pain were purchased at a total cost of less than EUR 7.8 million. OTC sales of salicylic acid containing ointments reached over 9,000 g/1,000 inhabitants during year 2001 (2).

Conclusion

There were no major changes in the OTC consumption and sales of drugs during 1996–2001. Drugs for GI diseases and analgesics attained the highest OTC sales, measured in DDD. Measured in money, the list was topped by analgesics, vitamins and minerals.

Literature

1. Apteekinhoidon käsikirja. Pharma Press, Helsinki, 2001

2. Finnish Statistics on Medicines 1996, 1997, 1998, 1999, 2000, 2001. National Agency for Medicines and Social Insurance Institution, Helsinki

3. Voipio T. Consumption of anti-inflammatory analgesics: the effect of the switch to OTC. TABU 2001;5:45-48

4. Virtamo J, Huttunen J. Beetakaroteenia pilleristä vai porkkanasta? Suomen Lääkärilehti 1996;9:944

Survey on TABU 2002

More of everything!

A telephone survey by Otantatutkimus Oy Finland was made to assess the significance of TABU Journal as compared to other producers/journals of drug information. The questions were addressed to 255 physicians and 80 pharmacists.

The physicians interviewed were first asked what sources of drug information did they remember and how they evaluated the information from various sources. TABU obtained a good overall score with the remark, however, that the practicality of the articles could be improved (Fig 1).

The physicians were also asked which producers of drug information could potentially influence their drug prescription practices. The impact of information from the drug industry was estimated less important and correspondingly, that from the National Agency of Medicines more important compared to the survey two years ago (Fig 2).

The final question "What topics should TABU cover in the future?" revealed a seemingly insatiable need for information, especially concerning new drugs and adverse drug reactions – the authentic answer quoted in the title speaks for itself.

Fig. 1. Your opinion of TABU/Finnish Medical Journal/Duodecim on the scale 4–10?

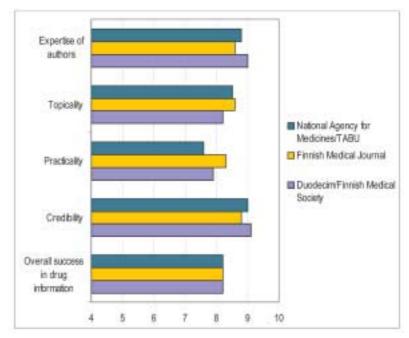


Fig. 2. Does information from any source influence your prescription habits? Which source?

