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Editorial

Self medication – part of responsible health care

The basic truth expressed by Paracelsus about 500 years ago about the difference between a poison and a medicine is still valid. Ultimately, all substances are toxic if the dose is sufficiently high. Then again, even a toxic substance could be a medicine if the dose is right.

The tendency which began in developed and industrialised countries at the start of the 1990s, to change the classification for the supply of medicinal products from a prescription only medicine to a self-medication product, appears still to be continuing. For a while, the general impression was that the therapeutic indications and medicines appropriate for self medication had been weeded out. The legal status of simvastatin, a well-known and widely used anti-cholesterol agent, as a prescription-only drug was nevertheless abolished last year in the UK with certain restrictions. This example, and the ongoing discussion in Europe about new possible self-medication indications (e.g. depression, diabetes, gout, hypertension, migraine and psoriasis), show that self-medication products have at least in some countries become part of the means to fulfil the political objectives concerning health.

Consumers and patients have been transformed from passive and ignorant healthcare targets to interest groups which emphasise the empowerment, the opportunity to exert influence and the right of choice of the individual. A similar effect is exerted by a chronic shortage of financing of the health care system in many countries, image advertising of medicines, and the increased media attention given to various health themes. Society is under the threat of becoming medicalised. This may lead to the excessive consumption of medicines and to harmful effects. The consumption of medicines in Finland (DDD/1,000 inhabitants/day) has increased during the first years of 2000 to become the highest in the Nordic countries.¹

In these circumstances, calm judgement is required from the authorities who decide on the legal status of medicines, in order that the observations of Paracelsus and modern day pharmacologists should not be disregarded in respect to the protection of the safe use of medicines and the promotion of public health. When talking about self-medication products, we forget that it was only a little while ago that they were prescription-only medicines, and that their long lists of adverse effects, warnings, contraindications and interactions have remained unchanged. A medicinal substance given the status of a self-medication product (e.g. terfenadine) may even become re-classified to prescription-only medicines, followed by total removal from sale due to adverse effects that have occurred in its use.

A medicine does not become safer to use once the status of self-medication is granted. With certain restrictions, its sale and use without a prescription may nevertheless be approved. The approval is made easier by ensuring professional pharmaceutical counselling associated with the purchase. The decision for self-medication status may also be enclosed with a provision to the marketing authorisation holder to supply the pharmacies background material in support of the counselling they are providing. This was done in Finland in 2002 with regard to an oral contraceptive for postcoital pregnancy prevention.

With regard to the access to self-medication products, consumers and patients of the EU countries are not equally placed but are very much dependent on in which country they are domiciled. The prescription classification of anti-inflammatory analgesics (ketoprofen, naproxen) and agents for the treatment of gastric hyperacidity (H₂ blockers, omeprazole), for example, varies from country to country. The EU Directive of 1992 on prescription classification has not markedly increased uniformity among the countries.

An EU regulation will come into effect October this year and make centralised decisions on self-medication status within the entire EU possible. In this case the product should constitute a significant innovation or the decision should be in the interests of patients at Community level. The differences among the EU countries are beginning slowly but surely to diminish. Another matter entirely is the fact that there is no regulation at Community level of retail outlets for self-medication products within the EU. The issue falls within the national competence. The principal rule in Europe is the sale of medicines via pharmacies.

In addition to the monitoring of the safety of medicines, the classification of legal status also involves a wider view on the health policy and change in the society. Citizens are expected to take responsibility for the treatment of their illnesses and the associated symptoms. With a changing environment, the 'gate keeper' should be able to adjust the decisions on self medication to the new circumstances. Finland is neither the first, nor the last, country to make these decisions. An essential constraint on the increased and sensible use of self-medication products is the operation of pharmacies on the professional premises supporting the general health policy. The situation would become different if the sale of medicines were to be entrusted to the hands of non-professionals and to be directed by competition.

¹ *Medicines Consumption in the Nordic Countries 1999–2003. NOMESCO 72:2004 (www.nom-nos.dk).*

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The vaccination programme as redesigned in Finland from the beginning of the year

With the vaccines used in the redesigned vaccination programme, Finnish children will, as before, be protected against severe infections caused by tuberculosis, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio and Haemophilus influenzae type b (Hib). Owing to the new combination vaccines the number of vaccinations required for good protection had been reduced considerably. With the introduction of the new vaccine products adverse effects are also expected to be reduced.

The aim of the new vaccination programme is to provide the population with the maximum possible cover through vaccines against preventable contagious diseases. The need for a reform in the vaccination programme is influenced by changes in the epidemiology of contagious diseases, the introduction of improved vaccines on to the market, and the adverse effects associated with vaccines.

During 2002 and 2003 changes were made in the national vaccination programme, which had remained unchanged for almost a decade. Target groups for the influenza vaccine were extended in the autumn of 2002 so that, besides the individuals in the category of conventional medical risk groups, the recommendation to vaccinate would also include all Finns of 65 years of age and older. The booster vaccination against diphtheria-tetanus-pertussis (dTap, aP = acellular pertussis) given to children of pre-school age was added to the vaccination programme at the beginning of 2003. Polio vaccinations (inactivated polio vaccine, IPV) at the ages of 11 and 16–18 were abandoned at the same time, because adequate protective immunity in Finland is provided by the vaccination programme consisting of four injections of the polio vaccine at pre-school age. Ad-

ditional booster injections are only required in exceptional cases.

Planning and decision-making in the vaccination programme

The Ministry of Social Affairs and Health (STM) is in charge of the general planning, guidelines and monitoring of the efforts involved in the prevention of communicable diseases. The actual vaccination programme is also decided upon at the Ministry, where the expert body on the prevention of transmissible disease is known as the Advisory Board on Communicable Diseases. The National Public Health Institute (KTL) is the expert institution involved. The national vaccination expert group, the vaccination recommendation working group of the KTL, and the various vaccine expert groups, are the experts who support the decision-making process concerned in the vaccination programme. The municipalities are responsible for the practical arrangements surrounding the vaccinations

In the design of a general vaccination programme consideration needs to be given to the importance of the preventable disease from the public health point of view, the severity of the disease and the risk of contracting the disease in various age groups, the maturity of immune

response of the individual being vaccinated, the efficacy of the vaccine, and any adverse effects from the viewpoint of both the individual and the society, including the operational and economical perspectives of health care.

The design of the national vaccination programme is always the result of compromise. The aim is to reach an adequate level of protection as early as possible and with as low doses of vaccine and as few adverse effects as possible. The decree of the STM on vaccinations and screening for communicable diseases during pregnancy provides the guidelines for vaccines associated schedules beginning from 1.1.2005 (Table 1 and 2)

Vaccinations for adults

All adults should make sure that they have received the cover of at least three tetanus, diphtheria and polio vaccinations. All adults should also be covered for measles, rubella and mumps either by having had the disease or by two MPR vaccine injections. If the vaccination cover in an adult is found to be inadequate as far as these vaccinations are concerned, the cover should be supplemented. Thereafter, a dT booster vaccination against diphtheria and tetanus should be given eve-

Table 1. Vaccines used in the general vaccination programme: (situation February 2005)

| Abbreviation | Vaccine |
|--------------|---|
| BCG | Tuberculosis vaccine (<i>Bacillus Calmette-Guerin</i>), BCG Vaccine SSI |
| DTaP-IPV-Hib | diphtheria = D, tetanus = T, acellular pertussis = aP, polio (IPV) and <i>Haemophilus influenzae</i> type b (Hib) vaccin, Pentavac |
| DTaP-IPV | diphtheria (D), tetanus (T), acellular pertussis (aP) and polio (IPV) vaccine, Tetravac |
| dtap | diphtheria (d), tetanus (t) and acellular pertussis (ap) vaccine, Boostrix |
| DT | diphtheria (D)- and tetanus (T) -vaccine |
| dT | diphtheria (d)- and tetanus (T) vaccine, diTeBooster |
| Hib | <i>Haemophilus influenzae</i> type b (Hib) vaccine, Hiberix |
| IPV | polio vaccine containing inactivated viruses of type 1, 2 and 3, Imovax Polio |
| MPR | measles (M), parotitis/mumps (P) and rubella (R) vaccine, MMR II |
| HAV | hepatitis A vaccine, Havrix |
| HBV | hepatitis B vaccine, Engerix-B |
| HAV-HBV | hepatitis A and hepatitis B vaccine, Twinrix |
| influenza | influenza vaccine |

The amount of antigen in the vaccines is indicated as follows:

| | |
|---------|------------------------|
| D, T, P | high amount of antigen |
| d, t, p | low amount of antigen |

Table 2. Vaccinations for children and adolescents

| Vaccine | Recommended age |
|--------------|-----------------|
| BCG | < 1 week |
| DTaP-IPV-Hib | 3 months |
| DTaP-IPV-Hib | 5 months |
| DTaP-IPV-Hib | 12 months |
| MPR I | 14–18 months |
| DTaP-IPV | 4 years |
| MPR II | 6 years |
| dtap | 14–15 years |

ry 10 years. A booster vaccination against polio (IPV) is required only in special circumstances.

Vaccinations for special groups

Hepatitis A and hepatitis B vaccinations

Individuals at increased risk of contracting hepatitis A or B due to their living circumstances are given hepatitis vaccinations in accordance with the indications supplied by the KTL.

Influenza vaccinations

Such special groups of the population as are at a considerable health risk imposed by influenza, are vaccinated against influenza every year before the start of the epidemic period. The KTL announces the vaccines which are to be used each year, including the vaccination indica-

tions, and is in charge of the distribution of influenza vaccines to the health centres in Finland. In autumn 2002 all Finns of 65 years of age and over were included in the groups receiving vaccination.

The recommendation also covers children of six months of age and over, who belong to medical risk groups, and who have no contraindications for vaccination. One dose of injection is usually adequate in the annual vaccinations. If the child is under the age of nine and has not been given an influenza vaccination before, one dose of the vaccine does not necessarily provide adequate cover. It is recommended that such children be given another equal dose about six months after the first one.

A Finnish study published in autumn 2004 (1) reviewed the burden of disease caused by influenza in children under the age of 13 during two periods of influenza, 2000–2001 and 2001–2002. In this study, the parents were advised to bring their child to the investigation clinic if fever or respiratory symptoms occurred. During the visit to the clinic a nasopharyngeal sample was taken for a virus culture. A total of 372 influenza episodes were documented during the study. The annual incidence of influenza in children under the age of three was 179/1,000, in children of 3–6 years of age it was 175/1,000 and in children of 7 years of age and over it was 142/1,000.

The most common complication associated with influenza was otitis with an almost 40% incidence in children under the age of three. This is the rate of incidence of otitis in small children in association with any upper respiratory virus infection. Antibiotic treatment was prescribed for various reasons in a total of 42% of the under three-year-olds.

The study indicated that especially influenza in the under three-year-olds with associated complications, medical treatment, and the parents' absence from work to care for their child, caused a significant burden from the disease on the children and their families. One of the conclusions the researchers drew was that vaccinating this age group against influenza may be beneficial.

At its meeting in November the national vaccination expert group (KRAR) discussed the influenza vaccination of small children in the light of the above information. The expert group suggests that the KTL summons a meeting of a broadly based working group to review the situation of influenza vaccinations for children, hoping for urgent dealing with the issue in the working group. The expert group (KRAR) is expecting a review of the working group and does not consider boosting the influenza vaccinations of children with a special campaign prior to the review to be necessary.

Transition period

Vaccinations introduced before 2005 are to be continued by special guidelines. These guidelines for the transition period will guarantee an equal basic cover for all children irrespective of the stage at which they are in the vaccination programme at the beginning of 2005. Vaccinations initiated before that will be supplemented with new vaccines from the beginning of 2005. This will diminish the use of individual vaccines.

Vaccination records

The forms for vaccination and the personalised health cards used at health care centres have been redesigned. Health care centres should take care to update their electronic data systems.

Vaccinations administered will be recorded in the individual's health and patient records, either in the adult or child vaccination forms or in the electronic health data system. Besides showing the personal data of the individual, the recorded data should show the date, trade name of vaccine and batch number of the vaccine including the site and route of administration. These details are necessary, for example, for studying individual adverse reactions and population vaccination cover. It is also recommended that vaccination details be included in the adult health card or national vaccination card, or both. Similarly, details of children's vaccinations are included in the child's own health card which is in the charge of its parents.

Vaccination programme accomplished

Vaccinations have been a routine for decades in Finnish families and health care centres. Prior to school age, the children are given a protection against nine severe diseases. Polio, measles, mumps and rubella, which are covered by the general vaccination programme, have already been eradicated in Finland. Tuberculosis, diphtheria, tetanus and severe diseases caused by *Haemophilus* spp. have almost totally disappeared. Whooping cough has occurred, but significantly less frequently compared with the period

prior to the vaccination programme. This good outcome is the result of the extensive use of effective vaccines in the country. Health care centre system which operates well makes vaccines available to all families; at least 93% of the children receive all the vaccinations in accordance with the Finnish vaccination programme.

Future challenges

Throughout the years, the attitude towards vaccinations in Finland has been mainly positive. Obtaining voluntary vaccinations has not, however, always been quite that clear. Parents want ever more detailed information about the vaccines on offer to their children and about the alternatives available. There is plenty of information on offer about vaccinations, but the quality of information varies greatly and the sources are also very varied. Use of the Internet has increased the availability of information to all citizens, and debates about vaccinations are carried out in e-mail groups. Knowledge about vaccinations among citizens can be increased and fears and wrong notions associated with vaccinations diminished by providing appropriate information. All doctors and health care professionals working in outpatient care should therefore be familiar with the vaccines of the general vaccination programme, their benefits and disadvantages.

Vaccines other than those included in the general vaccination programme are also given on health care centre appointments and at private doctors' offices. New vaccines, the inclusion of which in the general vaccination programme is not self-evident, have been and are being introduced on to the market. Boosting the vaccinations given in childhood and adolescence is important in adulthood.

In addition to the challenges imposed by the general vaccination programme, vaccination for travellers is also a big challenge to those involved in vaccination work, as long-distance travellers and those working abroad often need special vaccines. Those carrying out vaccinations nowadays are therefore expected to master a quantity of

such information on vaccination which previously belonged to the domain of only a few experts.

1 Heikkinen T, Silvennoinen H, Peltola V, Ziegler T, Vainionpaa R, Vuorinen T, Kainulainen L, Puhakka T, Jarsti T, Toikka P, Lehtinen P, Routi T, Juven T. Burden of influenza in children in the community. *J Infect Dis.* 2004;190: 1369-73. Epub 2004 Sep 15.

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The consumption of medicines in the Nordic countries 1999–2003

The Nordic Medico-Statistical Committee (Nomesco) has published drug statistics on the sales of the most important groups of drugs in the Nordic countries during 1999-2003. A few gleanings from the booklet Medicines Consumption in the Nordic Countries are presented below.

The consumption of medicines measured in defined daily doses (DDD/1,000 inhabitants/day) increased steadily in all the Nordic countries. The increased consumption is partly a result of the ageing population, as the use of medicines increases with age. Previously non-existent medical treatment for diseases, such as Alzheimer's disease and multiple sclerosis, have also been introduced in recent years. The increasing amount of money spent on medicines is mostly due to previous medicines being replaced by more recent and more expensive ones, which is especially shown in the increased medical costs involved in the treatment of psychoses and asthma.

Attempts have been made to reduce the increasing costs of medicines by the introduction of generic substitution in all countries. Generic substitution together with the simultaneous termination of patent protection, and parallel imports of certain important medicines, slowed down the increasing costs at least temporarily. This was most prominently exhibited by the sales of antacids, which actually dropped by over 20% in Sweden between 1999 and 2003.

A small selection of self-medication products was released for sale outside pharmacies in Denmark in 2001 and in Norway in 2003. This did not result in any significant changes in consumption. According to a Danish review, only about 15% of these particular products were sold in outlets other than pharmacies.

Medicines most frequently used

The most frequently used medicine in the Nordic countries was the low-dose acetylsalicylic acid indicated for the prevention of myocardial infarction and used by 5–10% of the population. The list of the ten top medicines in all the countries included furosemide, simvastatin and/or atorvastatin, and enalapril and/or ramipril in Sweden, Finland and Denmark. Among analgesics, paracetamol topped the list of most frequently sold medicines in Denmark, Sweden and Norway, and ibuprofen in Finland and Iceland. Among hypnotics and sedatives, zopiclone was included on the list of most frequently sold medicines in Iceland, Norway and Finland; another hyp-

notic included on list in Finland was temazepam.

The proportion of the ten most frequently sold medicinal substances with the consumption expressed as daily doses was 49% in Norway, and 23–28% in the other Nordic countries. Their share in the total cost of medicines was distinctly lower, 7–12%, i.e. the medicines most frequently used are mainly old, relatively low-cost products.

The medicines generating the highest costs of all in all the countries included proton pump inhibitors used for gastric ulcers, indigestion and reflux disease, and lipid-lowering agents. Measured by their therapeutic indications, the majority of medicines used were for the treatment of cardiovascular diseases, pain and psychiatric disorders.

Cardiovascular medicines

The consumption of cardiovascular drugs was rapidly further increased, which was mainly a result of the increased use of more recent drugs with an effect on the renin-angiotensin system, and cholesterol-lowering drugs. The biggest consumption of cholesterol-lowering drugs was seen

The consumption of medicines is presented as DDD, defined daily dose, in relation to the population and time period (DDD/1,000 inhabitants/day). The proportion of population that used the particular medicine daily as a daily dose is presented in promilles. The DDD is a unit used in international drug statistics based on the average adult daily dose for the main indication of the drug. For ease of reading, DDD/1,000 inhabitants/day has in this text been abbreviated to DID.

The figures in the text refer to the year 2003. Data from Faroes, Greenland and Åland is included the figures only.

in Norway, followed by Finland, whereas Denmark had the lowest consumption of all (Fig. 1).

The biggest difference in the group of antihypertensives was seen in the consumption of diuretics. The highest use was seen in Denmark (108 DID), where the use of thiazides alone accounted for almost half of the consumption, the lowest in Norway (42 DID). In Finland the use of thiazides alone was insignificant (5 DID), whereas the combined use of thiazides and potassium sparing diuretics in Finland (23 DID) was double the figure it reached in Sweden (12 DID) and about four times that in Denmark and Norway (6–7 DID).

The consumption of beta-blockers was highest in Finland (66 DID) and lowest in Denmark (27 DID). The level of use of calcium channel blockers did not vary significantly among the different countries (31–45 DID).

The level of use of substances with an effect on the renin-angioten-

sin system was highest in Finland (108 DID) and Norway (96 DID), whereas it was lowest in Denmark (74 DID). Differences within the group were seen: combination products of ACE inhibitors and diuretics were used to a higher extent in Finland (14 DID) than in the other countries (Sweden 2.5, Denmark 3.5, Norway 7.5 DID) whereas the use of angiotensin II antagonists was more common in Norway and Sweden (20–27 DID) compared with Finland (19 DID).

There was a two- to four-fold increase in the consumption of statins in all of the countries between 1999 and 2003. The consumption in Norway in 2003 was 98 DID, Sweden, Iceland and Finland 64–66 DID and Denmark 45 DID.

Hormones

The consumption of the contraceptive pill decreased slightly in Finland and Sweden, but it increased in the other Nordic countries. The use of

products for hormone replacement therapy decreased in Sweden, Norway and Iceland beginning from 1999, also followed by a decrease in Denmark and Finland in 2003.

Antidepressants and antipsychotics

The consumption of antidepressants continued to grow in all of the countries. The highest consumption of drugs of this group was seen in Iceland, and the lowest in Finland (Fig.). Use of serotonin selective drugs has increased in particular. This group contains less costly appropriate alternatives, and the consumption in the group measured in money increased to a lesser degree (35% in Finland) than when measured in daily doses (45%).

Treatment of psychosis has moved on to using relatively recent and more expensive drugs than before. In all the Nordic countries combined the use of antipsychotics increased only slightly, but their consumption

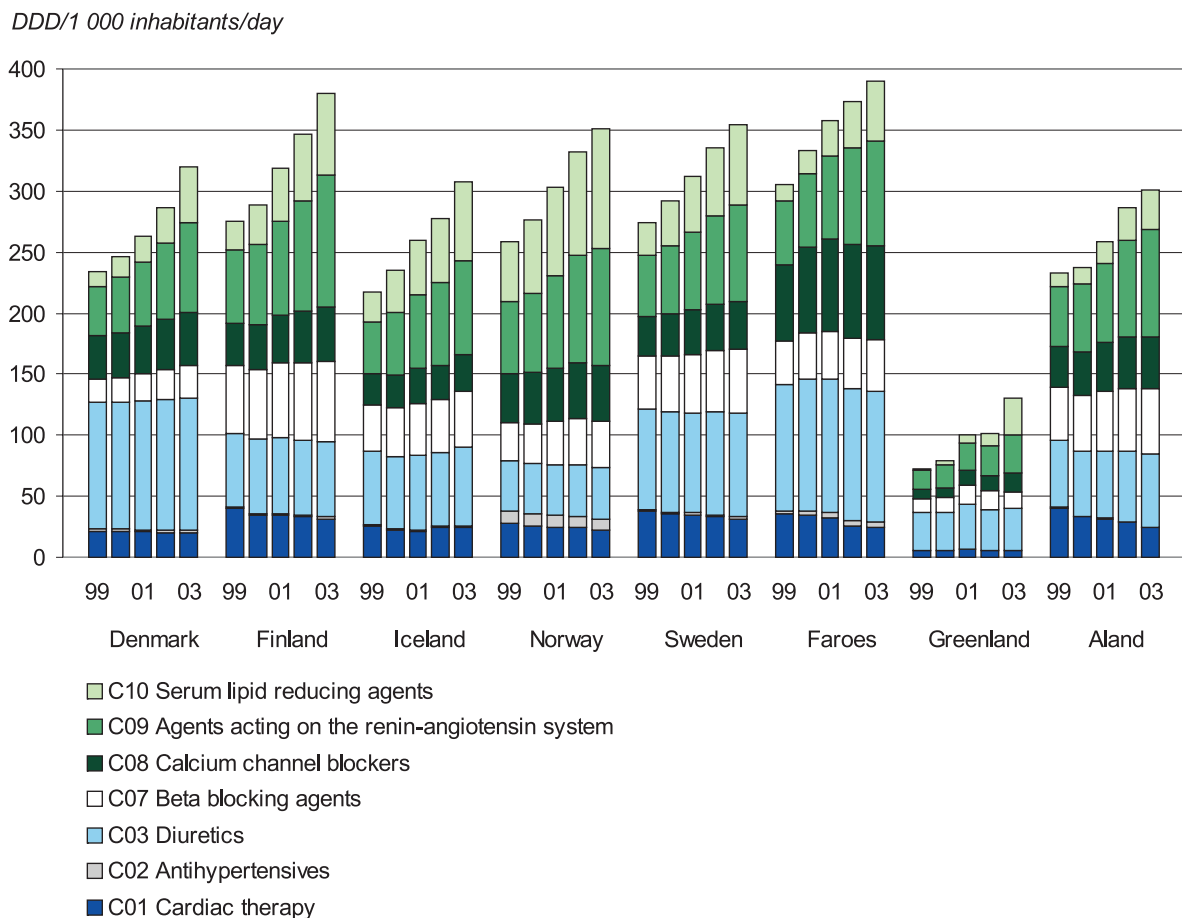


Fig. 1. Consumption of drugs for cardiovascular diseases 1990–2003

DDD/1 000 inhabitants/day

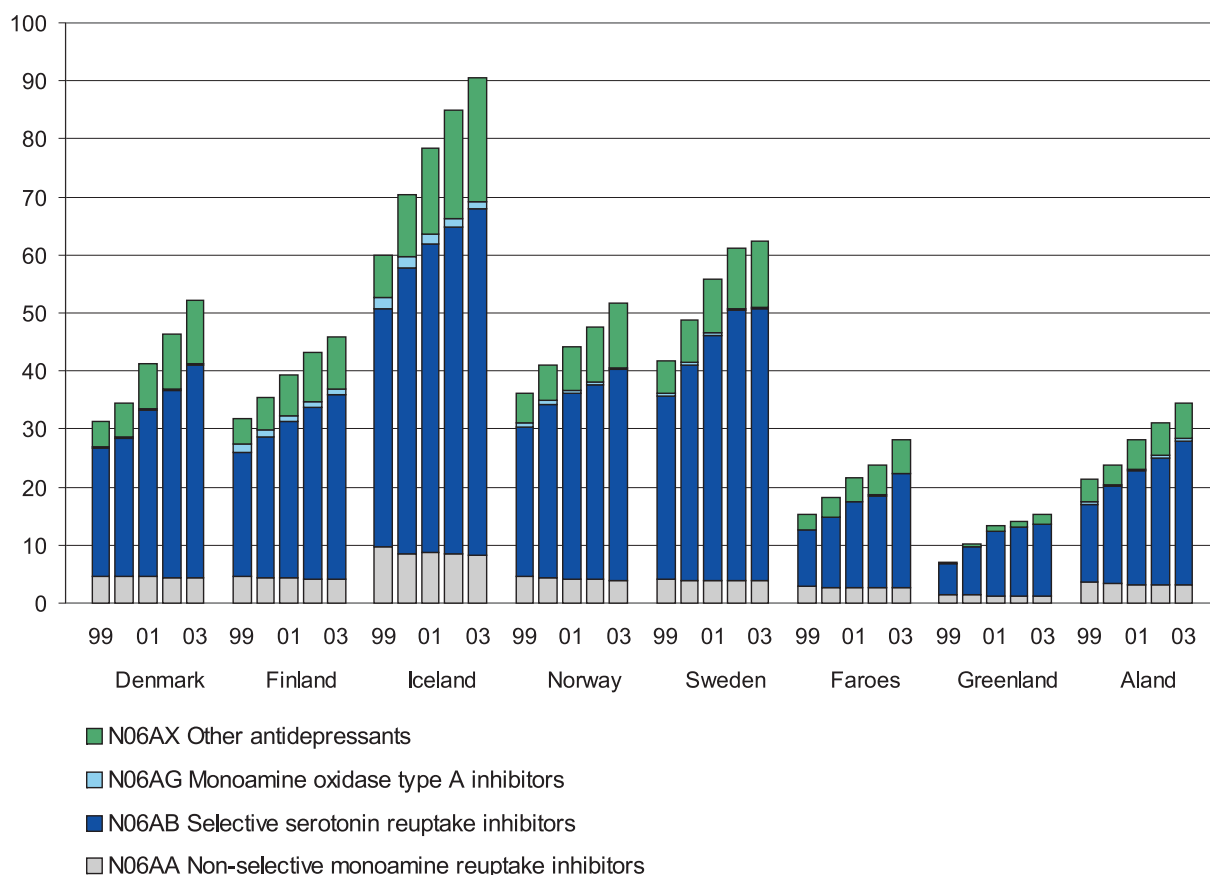


Fig. 1. Consumption of antidepressants 1990–2003

measured in money increased sharply by 62–138% depending on the country, between 1999 and 2003 (109% in Finland).

Antiasthmatics

The consumption of antiasthmatics has not increased in recent years, in fact, it is shown to have dropped in most of the countries instead (Fig. 3). This is misleading, and caused by statistics which show an increase in the use of combination products. Combination products have an established daily dose, and when both the active agents are taken separately, the same amount of medicine is calculated as two daily doses. Combination products should only be used in situations where it has not

been possible to control the symptoms with an inhaled corticosteroid and beta-2 agonists, administered as necessary, but this guideline does not appear to be adhered to and the use of combination products has increased rapidly, especially in Norway, Iceland and Finland. As a result, the treatment for asthma has become markedly more expensive in all the Nordic countries. The sales of drugs of the ATC Code R03A (beta-agonists and beta-agonist-corticosteroid combinations) measured in money increased in between 1999 and 2003 by 62% at the least (Denmark) and by 165% at the most (Iceland). In Finland, the sales increased by 121%.

Conclusion

The use of medicines in the Nordic countries is relatively uniform, including the challenges due to increased consumption faced by those responsible for the attempts to restrict the spiralling costs of medicines. Nevertheless, differences can also be discerned in the consumption. The lowest consumption of medicines is found in Denmark, whereas the biggest users are Sweden and Finland if all the defined daily doses are combined. However, the differences vary, and consequently, the consumption of one group of drugs may in any one country be the highest of all and that of another group the lowest.

DDD/1 000 inhabitants/day

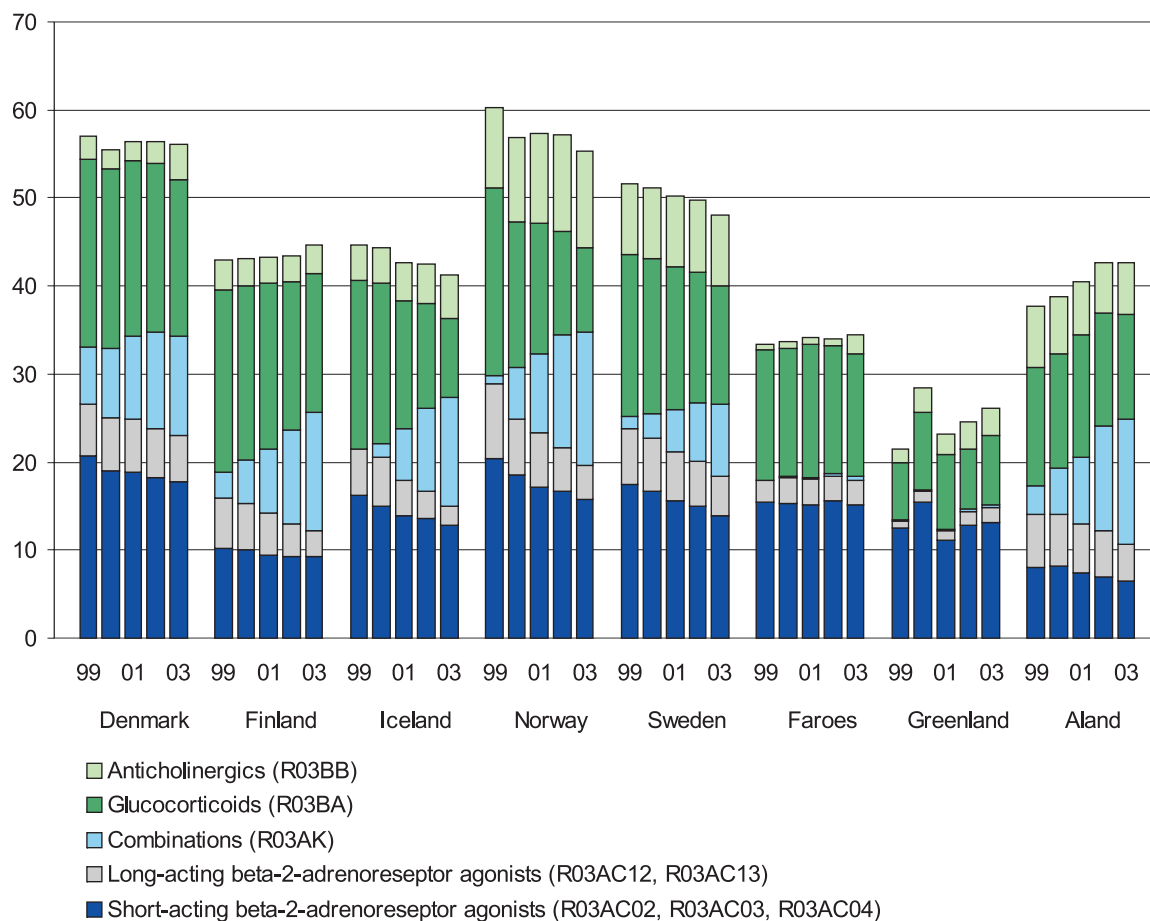
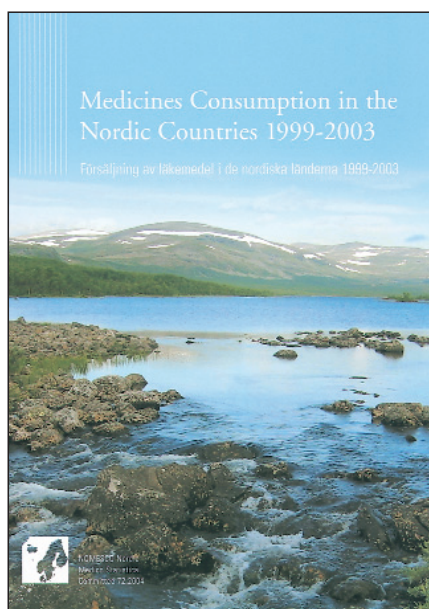


Fig. 3. Consumption of antiasthmatics 1990–2003



The booklet *Medicines Consumption in the Nordic countries* can be ordered by the website of the Nordic Medico-Statistical Committee www.nom.nos.dk
The publication can also be downloaded as a PDF file from the website.



The booklet *Finnish Statistics on Medicines* can be ordered by e-mail: salesstatistics@nam.fi

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Report 2002–2003 on endoprostheses completed

The recording of endoprosthetic surgical procedures has a long tradition in Finland. National data have been inserted in the same register ever since 1980, which is notable as a long uninterrupted period as far as the history of registers goes. It has produced valuable information for many and various purposes. By the end of 2003 the data on endoprostheses in the implant register maintained by the National Agency for Medicines consisted of the monitoring of a total of 180,446 endoprostheses. There are well over a million follow-up years.

The implant register has been maintained by the National Agency for Medicines since 1995, with the responsibility for supervising the permanent implants in humans and promoting the safe use of healthcare equipment such as implants.

Has the implant register had any impact in Finland?

There has been a nearly ten-fold increase in the use of endoprostheses in Finland during the past 20 years. However, the number of these operations does not yet correspond to the need for surgery among the population. For hip and knee joint endoprostheses a hundred operations in one year in a population of 100,000 was previously considered a good achievement. The requirement for surgery is suggested as being four-fold nowadays, making an approximate estimate. Several municipalities in Finland already match this number of endoprosthesis operations in fact, owing to the high proportion of elderly citizens in these municipalities. The effect the

publication of the number of operations has had on the decisions of municipalities to buy surgical procedures for their inhabitants has not been studied by the National Agency for Medicines. Nevertheless, it may be that the publication of the number of procedures promotes a more equal treatment of citizens in the various parts of the country; as the citizens may compare the numbers of operations in their own municipality with that in the neighbouring municipality, thereby putting pressure on decisions about healthcare resources.

Has the performance of endoprosthesis surgery improved?

Suddenly in the mid-1990s Finland had exceptionally high numbers of reoperations on endoprosthetic hip joint replacements. In an attempt to rectify the situation, the National Agency for Medicines increased the output of information about the implant register. In fact, the publication of data met with strong criticism from a section of the members of the orthopaedic profession. This has, however, since abated due to improved results. But is the use of endoprostheses undergoing a change of practice? In 2003, the ten most popular models of endoprostheses in hip joint surgery covered 85% of the total use. This is likely to be a consequence of the publication of the data on performance, especially in the endoprosthesis registers in the Nordic countries. Comprehensive research data are available on almost all models of the majority of endoprostheses in use nowadays.

Hip joint endoprosthesis surgery in the whole country in 1999 resul-

ted in reoperation in 24.6% of the cases. Nowadays the number of reoperations exceeds 20% of all hip joint endoprostheses in the areas of only six hospital districts. The main explanation even in these cases appears to be the insignificant increase in the number of first operations.

The success rates of certain models of endoprosthesis are very good in the whole country, both for hip and knee joints. Even the results on the unselected material in the country stand up to comparison at least with the series of results published world-wide. This promising development is likely to have been influenced by the training provided by manufacturers, importers and professional organisations.

Endoprosthesis procedures are gradually moving to larger units. From the viewpoint of the supervisory authority on the safety of medical devices, this development is no doubt greeted with joy. The Ministry of Social Affairs and Health has expressed its preparedness to stipulate recommendations for minimum numbers of operations in the endoprosthesis field within the public health care services. The favourable development in performance is the result of several inseparable components, but the performance of larger surgical units is likely to be superior, at least in the long term. The larger units have better opportunities for follow-up and research.

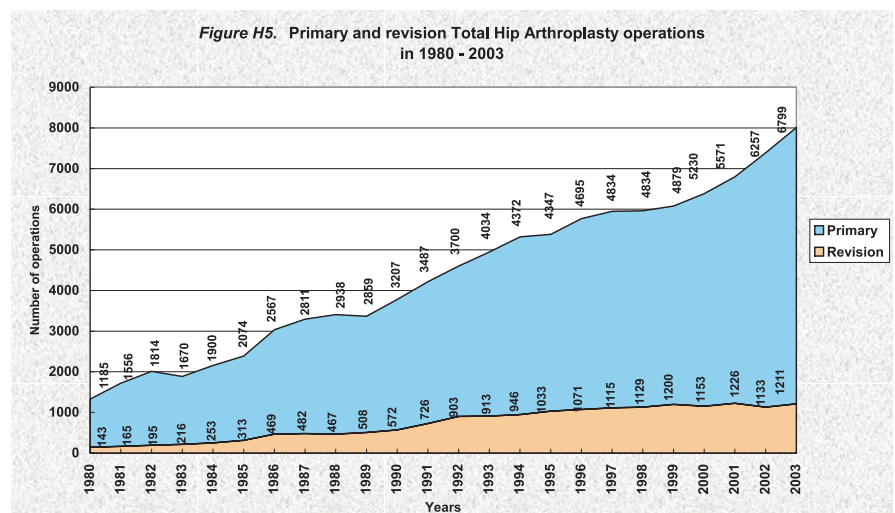
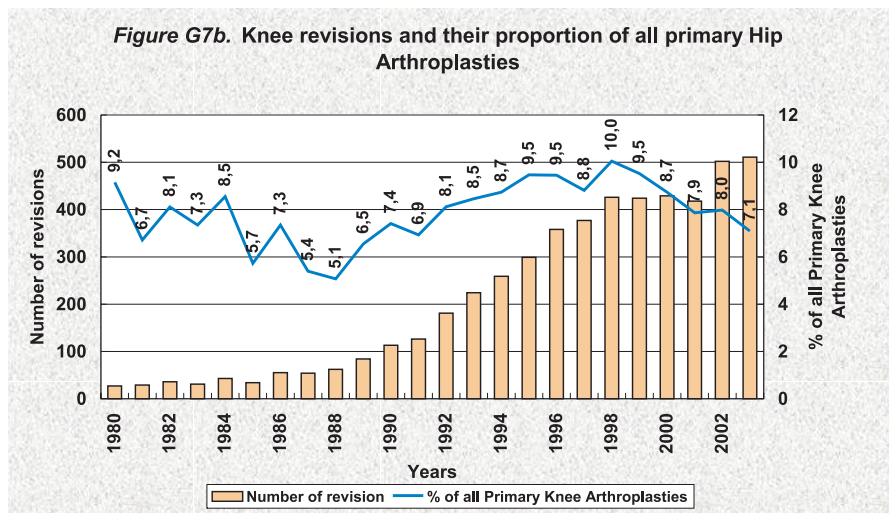
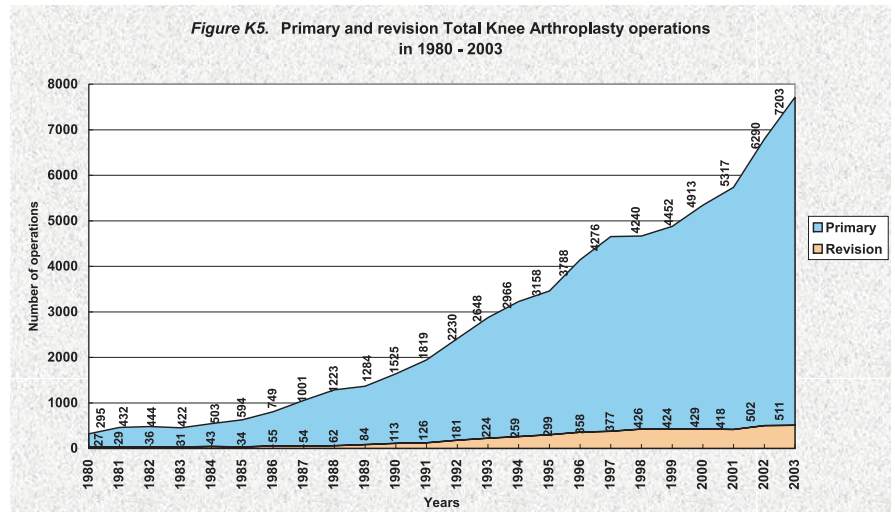
New significant happenings in the endoprosthesis field in the next few years will take place in the area of newly introduced or re-introduced sliding surface materials and the reintroduction of the coating of

prostheses. The use of coating material for hip joint replacements in Finland is probably the most extensive in the world in proportion to the population, as monitored by an independent register (n = 557). At present, however, in view of the fact that the material has been involved in only one reoperation, it is impossible to draw conclusions about the long-term success of the procedure. Finland has an evident obligation to follow up any developments in this procedure very carefully and report the results to the orthopaedic community.

As the performance of endoprosthesis procedures is improving, the register used in the monitoring of the performance should also be made more accurate. From the viewpoint of the medical devices safety authority, the most important project is the identification of the materials available. A project on an implant database is nearing its completion at the National Agency for Medicines, in which each component used will be individually identified. This is step towards an electronic data system. According to experiments carried out in Finland it is likely that the electronic system will occupy a position alongside the present reporting system without completely replacing it.

Prior to entering the data in the register the data will be manually examined twice by two different parties to ensure that high reliability is retained. The data are examined at the National Agency for Medicines prior to inclusion in the register, and hospitals are offered the opportunity to check their own individual data annually. Some hospitals have used this opportunity. On inspection, most of the hospitals have found that their total data correspond to their own files.

The compilation of recorded data is not possible without their systematic collection from hospitals. Data collection is a labour intensive operation, and the filling of forms often takes place after the operation when there is pressure to move on to the next job. The accuracy of the



information as it stands is worthy of congratulation, and the compliments go to all participants in the collection procedure!

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