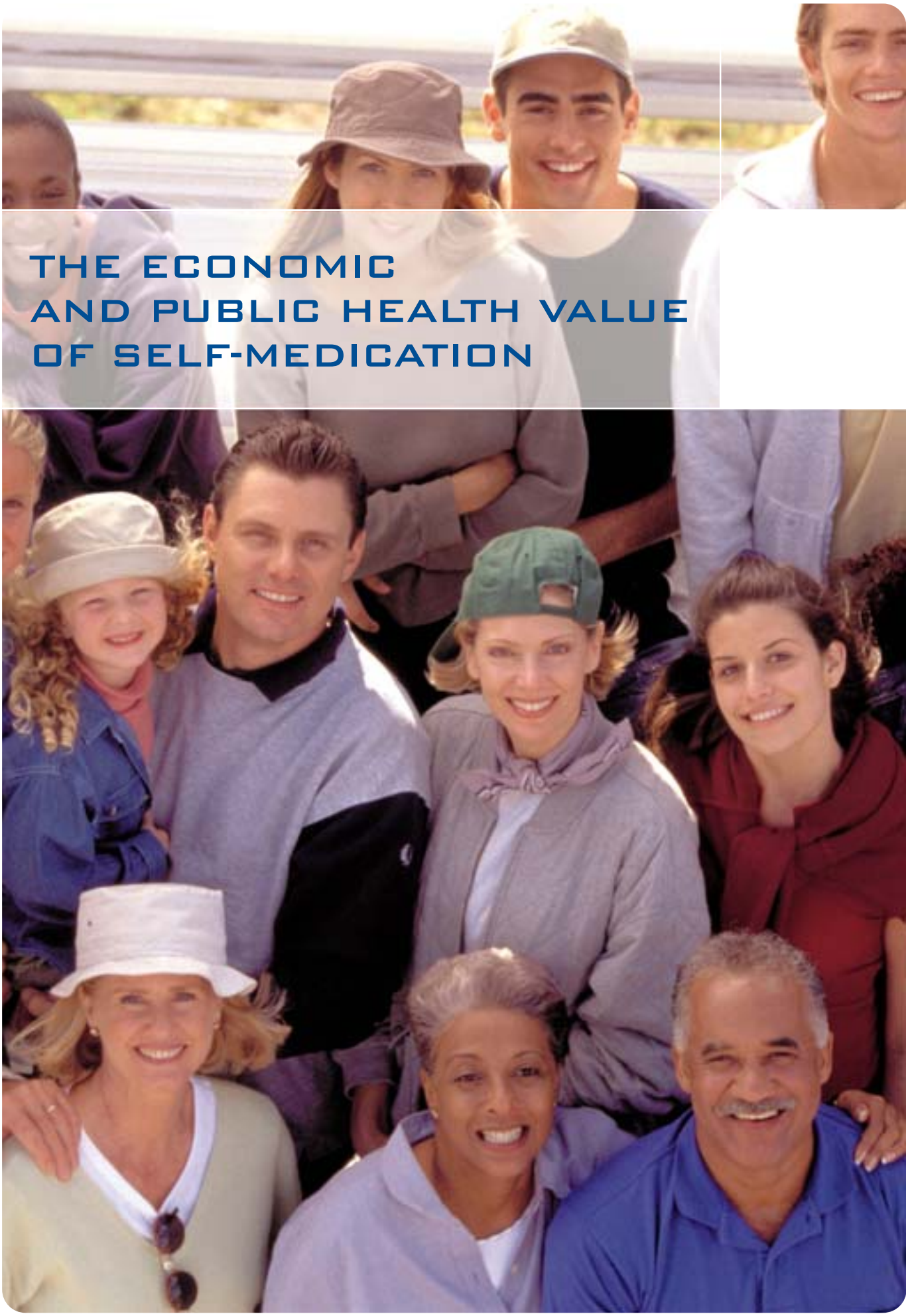


THE ECONOMIC AND PUBLIC HEALTH VALUE OF SELF-MEDICATION

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Responsible self-medication considerably reduces the expenses of social security systems and healthcare costs for national economies. Based on a detailed analysis of seven European countries, total annual savings resulting from a move of 5% of prescribed medications to self-medication exceed 16 billion euros. This demonstrates that self-medication makes a significant contribution to relieving the financial burden of the European healthcare systems.

At the same time, the move of medicines from prescription to non-prescription status and the availability of a growing range of non-prescription medicines make an important contribution to public health. Case studies on vaginal mycosis, smoking cessation and heart disease prevention demonstrate how innovative non-prescription medicines may improve treatment as well as prevention of illness.

Whenever the economic and public health benefits of self-medication are discussed, it is important to address inequalities in health. This means that not every citizen may feel sufficiently confident to practise responsible self-medication. It is also evident that not everybody has the financial means to do so. The whole notion of responsible self-medication -both in a traditional sense and in the future- is based on the concept of choice. Allowing individuals certain options when they suffer minor, self-limiting or chronic diseases is the fundamental consideration behind responsible self-medication in Europe, and therefore also behind this study. This means that any move of medicines from prescription to non-prescription status should be disconnected from considerations of their reimbursement by a social security institution. It is equally important to ensure that any measure affecting their reimbursement covers a whole category of products / indications to avoid unproductive substitution effects.

In order to make concrete progress with regard to an appropriate self-medication policy, it is recommended to take a number of measures, including some allowing better communication on non-prescription medicines. These should enable manufacturers to produce patient leaflets that guide medicines users in an effective way, permit advertising for all non-prescription medicines in all media and leave flexibility in the use of trade names. Moreover, there is a need for efficient marketing authorisation procedures that recognise the well-known safety profile of many non-prescription medicines. Speedy and transparent mechanisms to change a product's classification status from prescription to non-prescription are also needed, together with incentives for manufacturers to carry out the related scientific work. Free pricing for manufacturers will ensure a competitive commercial environment with the best customer service.

AESGP hopes that this study will make a useful contribution to the ongoing debates on how to best design healthcare systems in the future. All constructive remarks are welcome.

June 2004

BACKGROUND

Responsible self-medication is nowadays widely recognised as playing an important part in the healthcare systems of Europe. Contributing factors to this recognition have been the growing importance of the individual's responsibility for his/her health as well as the need for social security systems and healthcare services to control expenses.

A number of studies have demonstrated the public health value of responsible self-medication and have tried to quantify its economic benefits. Research findings on this subject were published by AESGP in a document from May 1998 entitled "Encouraging self-medication can reduce the healthcare cost burden: An Economic Analysis of Self-Medication". This study[1] included a review of research projects carried out in some European countries. In the Foreword, the then President of the international umbrella organisation of health insurance groups (Association Internationale de la Mutualité, AIM) expressed his appreciation for the study and put it in a long-term perspective.

Following numerous requests, AESGP decided to carry out an update of this study and to enlarge the research into the area of public health. This includes in particular considerations around a study AESGP carried out in 2001 for the European Commission's Directorate-General Health and Consumer Policy entitled "Development of an information policy for medicinal products"[2], which primarily looked at the information needs in relation to new indications for self-medication. An open debate on a larger range of indications for non-prescription medicines than in the past is in full swing.

1. http://www.aesgp.be/encour/index-enc.html
2. http://www.aesgp.be/ResearchProject/FinalReport.pdf

PART I:

ANALYSIS OF THE BENEFITS OF SELF-MEDICATION BASED ON AN ECONOMIC MODEL

Introduction

The objective of this part of the study is to develop a general model that analyses the impact derived from moving patients from obtaining doctor prescriptions to treat minor illnesses to responsible self-medication with non-prescription medicines. It analyses the economic and financial impact of such a move on the most significant stakeholders, with the aim of increasing the evidence base of the economic value of self-medication and of demonstrating the incremental benefits of an increase in the levels of self-medication for the economy as a whole.

The analysis indicates the most important effects of self-medication in relation to the health economy. These include cost reductions in the field of outpatient medical care and medicine costs and, as a result, a relieving effect on public funds. The direct and indirect financial effects on the economy have also been calculated.

The model assumes that there is a substitution effect between prescribed and not prescribed medications. Market analysis using statistical data shows that there is a direct relationship between the level of doctor prescriptions for minor illnesses and the level of self-medication with non-prescription medicines for these illnesses.

INTRODUCTION

The situation has been particularly well documented for the German market, where this substitution effect could be validated and quantified on the basis of the movements in the German medicines market [3]. Figure 1 shows the substitution effect on the German market of volume changes in five particular years marked by political measures affecting the pharmaceutical sector.

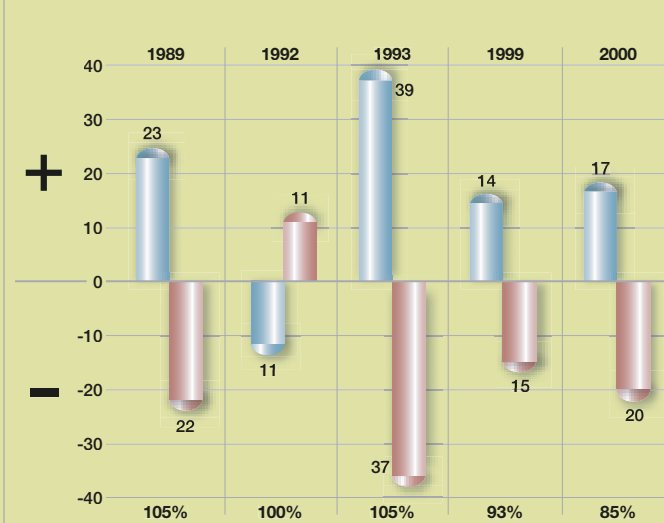
Figure 1 shows that falls in the number of products prescribed as a result of these measures coincided with almost identical rises in the number of self-medication packs that were bought in the years 1989, 1993, 1999 and 2000. In 1992 there was an opposite effect which can be attributed to doctors prescribing higher volumes in anticipation of impending cost-cutting measures through the Healthcare Reform Law *(Gesundheitsstrukturgesetz)*. In that year the increase in prescriptions caused a downward effect on self-medication volumes.

This market substitution effect justifies a direct comparison via a cost / benefit analysis of doctor prescriptions for products used to treat minor illnesses versus self-medication with non-prescription medicines to treat the same minor illnesses.

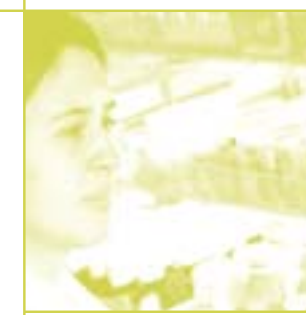
Given the difference in social security systems in Europe, the correlation between cost-containment measures and increased self-medication may not be as clear as in the German example. However, it is plausible that some correlation exists in all countries.

FIGURE 1

THE SUBSTITUTION RELATIONSHIPS BETWEEN DOCTORS´ PRESCRIPTIONS AND SELF-MEDICATION



3. May U. Selbstmedikation in Deutschland. Eine ökonomische und gesundheitspolitische Analyse. Wissenschaftliche Verlagsgesellschaft mbH Stuttgart (2002). Market analysis by the author based on IMS data.



MODEL FOR A EUROPE-WIDE ANALYSIS

The starting point for the study has been to establish a model that analyses the impact of moving patients from obtaining a prescription from a medical doctor to responsible self-medication. In this model, a certain volume of prescribed medications for minor illnesses is replaced by self-medication with non-prescription medicines.

Wide research has shown that at least 5% of all prescriptions for medicines are related to the treatment of minor illnesses. For example, it has been estimated in the United Kingdom [4] that 14% of all prescriptions in 1996 were related to minor ailments. An Italian report from the same year [5] quantified the medicines involved in treating minor illnesses at around 15% of the total Italian pharmaceutical market at ex-factory prices.

The general assumption in the model of a 5% shift of the total prescribed volume to self-medication can therefore be viewed as conservative as it only corresponds to about one third of the prescribed items to treat minor illnesses in a given country. In a slightly different approach, the analysis of the German market is based on the assumption that one third of the prescribed non-prescription market (representing 100 million packs) is shifted to self-medication.

4. British Market Research Bureau (UK, May 1997).
5. Research Centre on Health Management (Ce.R.G.A.S.), L. Bocconi Business University (Italy, 1996).

ELEMENTS OF THE ANALYSIS

The general approach is summarised in the Overview Table, which shows the impact on the main parties affected when a volume shift of prescribed items to self-medication takes place. After each party, a plus or minus sign in brackets shows how an increase in self-medication would affect it. A plus sign means that the shift would have a positive effect while a minus sign represents a negative effect in the sense of a financial or qualitative burden. The details of the impact and affected parties are described underneath the table.

TABLE 1

OVERVIEW TABLE

Impact of a volume shift of prescribed items to self-medication

Type of impact	Affected party	
Treatment by doctor	Doctors Patients Public funds	- + +
Treatment with medicines	Patients Public funds	- +
Patient co-payments	Patients Public funds	+ -
Freed up doctors' time	Patients Doctors	+ +
Absence from work caused by treatment	National economy Employers	+ +
Absence from work caused by illness	National economy Employers	+ +
Travel: a) Time-related b) Travel-related	 Patients Patients	 + +

Type of impact and affected party

Treatment by doctor

A reduction in the number of doctor visits is one of the main outcomes when patients choose to self-medicate. The average number of prescribed items per doctor visit indicates how many doctor visits correspond statistically to a specific number of prescribed medications and how many doctor visits can be avoided when replacing prescribed items by self-medication. In order to calculate the cost of these avoided doctor visits, their number is multiplied by the average cost of a visit for a minor ailment.

The doctor-related costs affect different parties in different ways depending on the healthcare system in a particular country. In some countries, doctors are paid a consultation fee by the patient. Therefore the doctor loses the fee when a patient chooses to self-medicate. In other countries, doctors are remunerated by public funds on the basis of points awarded for different forms of consultation, in which case self-medication also reduces the doctor's income. In a third group of countries, self-medication has an impact mainly on public funds but not on the rest of the parties involved. The cost of enlarged self-medication to doctors has therefore not been quantified in this study.

Treatment with medicines

When fewer medicines are prescribed and this volume is replaced by self-medication, this represents a saving for public funds. On the other hand, there is a replacement cost for patients as the latter will have to pay the full price of the medicine. Conversely, if patients decide to go to the doctor to get a prescribed and reimbursed medicine, the cost will mainly be borne by public funds. The impact of a volume shift currently paid out of public funds in the model is based on a calculation of the average price of the products shifted. Given that the products considered are used in the treatment of minor illnesses, the financial impact has been taken based on the average price of a non-prescription pack in each country.

Patient co-payments

In case patients choose to self-medicate they spend more on their medication. As on the other hand they will not have to contribute to the cost of the medication through co-payments on prescribed medication that are levied in certain countries, their overall disbursement will not change significantly in the countries with a co-payment system. The financial impact on patients has not been calculated in the model but it is not unrealistic to assume that the decrease in co-payments sometimes exceeds the cost of the self-medication product.

The saving to public funds has been calculated as the difference between the total cost of the medication and the co-payment patients would pay in case they decided to go to the doctor and get a prescribed medication.

TYPE OF IMPACT AND AFFECTED PARTY

FREED UP DOCTORS' TIME

A volume shift to self-medication would also have an impact on doctors' time. Fewer consultations on minor illnesses would free up time that could be spent on longer consultations for more serious conditions and reduce waiting time in the doctor's surgery, thus providing a real impact on the quality of care.

The model calculates freed up doctors' time based on the total number of medical doctors per country. Given that in practice it is the general practitioners who usually deal with minor conditions, the freed up time per general practitioner is considerably more than indicated in this study. This benefit has however proved impossible to evaluate in financial terms.

ABSENCE FROM WORK CAUSED BY TREATMENT

This item represents absence from work attributable to patients seeking treatment during working hours. Two assumptions have been made:

- 50% of doctor visits are made by the active population.
- 25% of these persons visit the doctor during working hours.

This means that the average number of doctor visits avoided has been divided by a factor of 8 (25% of 50%). The resulting figure has been multiplied by the treatment time, based on the average time missed from work, and by the cost to employers for each working day of missed time. It has been assumed that there is no loss of productivity to the national economy for absences lasting less than one day.

ABSENCE FROM WORK CAUSED BY ILLNESS

It has been assumed that people are absent from work for a shorter period of time when they practise responsible self-medication than when they go to see a doctor as they generally return to work sooner without official endorsement from a doctor that they are ill.

This item represents the average cost to the employer in lost compensation and to the national economy in lost productivity for each working day missed due to illness due to minor ailments. It has been estimated in the model that 10% of working days lost for absences lasting less than three days attributable to minor ailments could be avoided through responsible self-medication.

TRAVEL-RELATED COSTS

Travelling to the doctor and the pharmacy involves time and transportation costs. It has been proven that patients spend less time going to the pharmacy than going to the doctor, and that travel-related costs are also higher when going to both the doctor and the pharmacy than only to the pharmacy.

As visits to the pharmacy do not need an appointment and can be made during lunch hour or after work, no loss of working time has been assumed for purchases of non-prescription medicines.

CORRELATION BETWEEN THE VARIOUS SAVINGS

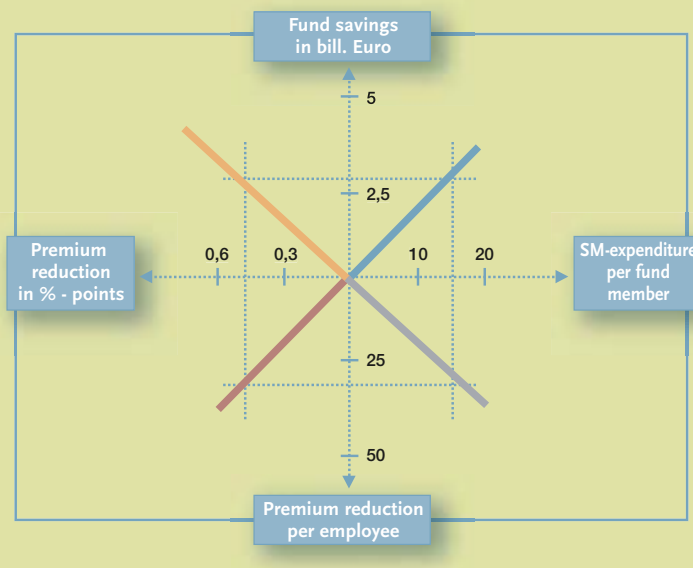
FINANCIAL IMPLICATIONS OF VOLUME SHIFTS TOWARDS SELF-MEDICATION

There is a financial correlation between the savings to public funds and savings to individuals when an extension in self-medication occurs.

Figure 2 shows the financial effects of self-medication on the German statutory health insurance (SHI) funds and their members [6].

FIGURE 2

FINANCIAL EFFECTS OF SELF-MEDICATION ON THE SHI FUNDS AND THEIR MEMBERS



Source: Uwe May. Selbstmedikation in Deutschland. Eine ökonomische und gesundheitspolitische Analyse. Wissenschaftliche Verlagsgesellschaft mbH Stuttgart 2002.

6. Source: May U. Selbstmedikation in Deutschland. Eine ökonomische und gesundheitspolitische Analyse. Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart (2002).

Correlation between the various savings

There are different financial relationships between the level of self-medication, the level of savings for public health insurance funds, premium contributions in relation to self-medication and the individual financial burden on each fund member.

Top right

In the top right quadrant, the horizontal axis represents self-medication spending in euros per insured fund member. The vertical axis indicates the savings for public funds in billion euros. The blue line in the top right quadrant shows how the savings for public health insurance funds rise through an increase in the individual expenditure on self-medication. As the level of savings for the SHI funds is proportional to the rate of substitution through self-medication, the blue line is straight. An increase in spend per fund member of €10 leads to savings for the SHI of €2.5 billion.

Top left

In the top left quadrant, the green line shows the potential reduction or limitation of the increase in the per capita premium payable to the SHI funds in terms of percentage points following the savings for the public health insurance. The premise that savings made by the SHI funds will be returned to fund members in the form of payment reductions or a limitation of the payment increase is justified by the general principle of global equivalence (no-profit principle) in the SHI.

Bottom left

In the bottom left quadrant, the pink line shows the relationship between the reduction in general payments to funds in terms of percentage points and the reduction in the average contribution to the premium per employee in euros. In other words; it shows by how many euros the employee's contribution to the public health insurance diminishes.

Bottom right

In the bottom right quadrant, the yellow line shows the relationship between the premium reduction per employee (the savings resulting from self-medication) and the increased self-medication expenditure per fund member, showing that there is a net positive financial effect per fund member. In the German case, a self-medication expenditure of €10 per fund member has a positive financial effect for each member of €18.

The diagram allows other constellations of self-medication expenditure. Any point of the blue line can be selected and plotted horizontally and vertically against the other three lines in the other three quadrants to get all the relevant figures. The model proves that whatever the level of self-medication, it leads to a total economic saving effect.

PRACTICAL APPLICATION OF THE MODEL

The model described above has been applied to selected countries around Europe. The results of this analysis for individual countries are set forth in the following pages.

COUNTRY ANALYSES
AUSTRIA

AUSTRIA

The Austrian model is based on the assumption that 5% of the volume of reimbursed medications (made up of prescription and non-prescription medicines) is being shifted to self-medication. Data for 2002 [7] (see Table 1 (Austria)) show that the total reimbursed market was 92.454 million packs. A 5% volume shift to self-medication would therefore correspond to 4.623 million packs.

TABLE 1
(AUSTRIA)

AUSTRIA	
Pharmaceutical market in 2002	**Packs**
Total pharmaceutical market, of which: distributed in pharmacies distributed in doctors' pharmacies	172 338 000 151 752 300 20 585 700
Total prescription market, of which: Reimbursable Not reimbursable	125 527 700 86 802 122 38 725 578
Total non-prescription market (registered products only), of which: Reimbursed Not reimbursed	46 810 300 5 651 700 41 158 600
Total reimbursed market	92 453 822
Substitution volume (5% of the reimbursed market)	4 622 691

7. IMS Health (2003).

COUNTRY ANALYSES
AUSTRIA

Table 2 (Austria) shows the impact of a shift of 4.6 million reimbursed packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(AUSTRIA)

AUSTRIA

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 5% equivalent to 4.623 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	2.854 million fewer doctor consultations	124.556
Treatment with medicines	Public funds	+	4.623 million fewer medicine packs	28.661
Patient co-payment	Public funds	-	3.606 million fewer co-payments	-15.324
Savings for public funds				137.892
Absence from work caused by treatment	Employers	+	66 879 fewer working days	12.236
Absence from work caused by illness	Employers National Economy	+	326 600 fewer working days	80.154
Savings for employers and national economy				92.390
Total annual savings				230.283

COUNTRY ANALYSES
AUSTRIA

Freed up doctors' time: With an average estimated time of 10 minutes per consultation, time freed up as a result of the lower number of doctor visit for minor ailments would represent 476 000 doctor working hours per annum or 13 hours per doctor per year.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (Austria).

TABLE 3
(AUSTRIA)

AUSTRIA

Statistical data

Number of medical doctors[8]	36 531
Average number of prescribed items per doctor visit[9]	1.62
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	2.854 1.427 0.357
Cost of a doctor visit[10]	€43.65
Average price of a non-prescription medicine[11]	€6.20
Patient co-payment per prescribed item in 2003 (22% of people are exempted)	€4.25
Total population[12]	8 131 111
People in employment (40%)[13]	3 266 000
Total working days lost per annum due to illness lasting less than three days (1 working day/person/year)[14], of which an assumed 10% reduction represents	3 266 000 326 600
Average time missed from work due to a doctor visit[15], of which it is assumed 25% is made during working hours	90 minutes
Avoided working days (of 8 hours) missed for doctor visits	66 879
Average cost of one missed working day to the employer[16]	€182.96
Average loss of productivity of one missed working day to the economy[17]	€245.42

8. Statistisches Zentralamt (2002).
9. HVB - Hauptverband der österreichischen Sozialversicherungsträger (2001).
10. HVB (2001).
11. IGEPHA (2003).
12. Statistisches Zentralamt (2001).
13. Statistisches Zentralamt (2001).
14. Statistisches Zentralamt (2001).
15. Theurl Study (1998).
16. Statistisches Zentralamt (2000).
17. Statistisches Zentralamt (2001).

COUNTRY ANALYSES
France

FRANCE

According to data from 2002[18], the total pharmaceutical market volume in France was 2 950 million packs. 10% were self-medication products, 36% reimbursed non-prescription product and 54% reimbursed prescription products. The assumption has been to shift 5% or 133.4 million reimbursed packs (prescription and non-prescription) to self-medication.

TABLE 1
(FRANCE)

FRANCE	
Pharmaceutical market in 2002	**Packs (millions)**
Total pharmaceutical market	2 950
Prescription reimbursed	1 597
Non-prescription reimbursed	1 071
Total reimbursed	2 668
Self-medication (non-prescription, not reimbursed)	282
Substitution volume (5% of the reimbursed market)	133.4

18. IMS Health (2003).

COUNTRY ANALYSES
FRANCE

Table 2 (France) shows the impact of a shift of 133.4 million reimbursed packs to self-medication and the related possible savings for public funds, employers and the national economy.

Freed up doctors' time: With an average estimated time of 10 minutes per consultation, time freed up as a result of the lower number of doctor visit for minor ailments would represent 6.091 million doctor working hours per annum or 25 hours per doctor per year.

TABLE 2
(FRANCE)

FRANCE

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 5% equivalent to 133.4 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	36.548 million fewer doctor consultations	730.959
Treatment with medicines	Public funds	+	133.4 million fewer medicine packs	727.030
Savings for public funds				**1 457.989**
Absence from work caused by treatment	Employers	+	1 631 605 fewer working days	278.678
Absence from work caused by illness	Employers National economy	+ +	2 276 890 fewer working days	745.471
Savings for employers and national economy				**1 024.149**
Total annual savings				**2 482.138**

COUNTRY ANALYSES
FRANCE

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (France).

TABLE 3
(FRANCE)

FRANCE	
Statistical data	
Number of medical doctors	245 585
Average number of prescribed items per doctor visit [19]	3.65
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	36.548 18.274 4.569
Cost of a doctor visit	€20.00
Average price of a non-prescription medicine [20]	€5.45
Total population (2002) [21]	61 230 000
People in employment (37.2%) [22]	22 768 900
Total working days lost per annum due to illness lasting less than three days (1 working day/person/year) [23], of which an assumed 10% reduction represents	22 768 900 2 276 890
Average time missed from work due to a doctor visit [24], of which it is assumed 50% is made during working hours	150 minutes
Avoided working days (of 7 hours) missed for doctor visits	1 631 605
Average cost of one missed working day (of 7 hours) to the employer [25]	€170.80
Average loss of productivity of one missed working day to the economy [26]	€327.40

19. Thales (2002).
20. Afipa (2003).
21. Eurostat (2002.)
22. INSEE, Comptes Nationaux, Division Emploi (2001).
23. INSEE, Comptes Nationaux, Division Emploi (2001).
24. Afipa (2003).
25. France 2000, La dynamique des salaires et du coût du travail entre 1996 et 2000. France Portrait social (2003/2004).
26. INSEE, Comptes Nationaux (2002).

COUNTRY ANALYSES
GERMANY

GERMANY

In Germany, the approach has been slightly different in that it considered the effect of shifting 100 million packs of non-prescription medicines prescribed by doctors to self-medication. These 100 million packs represented around 10% of the total prescribed market in 2001, 11.5% of the total non-prescription market and 35.2% of the prescribed non-prescription sector.

TABLE 1
(GERMANY)

GERMANY	
Pharmaceutical market in 2001	**Packs (millions)**
Total pharmaceutical market	1 660
•Prescription	699
Non-prescription, of which:	868
•Prescribed non-prescription	284
•Self-medication in the pharmacy	584
•Self-medication with medicinal products available outside the pharmacy	93
Total prescribed	983
Substitution volume (35.2% of the prescribed non-prescription market)	100

COUNTRY ANALYSES
GERMANY

Table 2 (Germany) shows the impact of a shift of 100 million prescribed non-prescription packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(GERMANY)

GERMANY

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 35.2% of the prescribed non-prescription market equivalent to 100 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	77 million fewer doctor consultations	1 963.500
Treatment with medicines	Public funds	+	100 million fewer medicine packs	845.000
Rebate to the SHI	Public funds	-	5% on €845 million	-42.250
Patient co-payment	Public funds	-	77 million fewer co-payments	-312.000
Savings for public funds				**2 454.250**
Absence from work caused by treatment	Employers	+	2 100 000 days	430.500
Absence from work caused by illness	Employers National Economy	+	2 500 000 days	767.000
Savings for employers and national economy				**1 197.500**
Total annual savings				**3 651.750**

COUNTRY ANALYSES
GERMANY

Freed up doctors' time: With an average time of 15 minutes per consultation[27], time freed up as a result of the lower number of doctor visit for minor ailments represents 19.25 million doctor working hours per annum, or 51 hours per doctor per year.

The statistical data to evaluate the impact of this 35.2% volume shift and their sources are set out in Table 3 (Germany).

TABLE 3
(GERMANY)

GERMANY	
Statistical data	
Number of medical doctors	381 000
Average number of prescribed items per doctor visit	1.3
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	77.000 38.500 9.625
Cost of a doctor visit	€25.50
Average price of a non-prescription medicine	€8.45
Average patient co-payment per prescribed item (considering 39% of people are exempted)	€3.12
Total population in 2001 [28]	82 278 000
Active population (49.2%)[29]	40 550 000
Total working days lost per annum due to illness lasting less than three days (1.62 working days/person/year), of which an assumed 10% reduction represents	25.0 2.5
Average time missed from work due to a doctor visit, of which it is assumed 25% is made during working hours	101 minutes
Avoided working days (of 8 hours) missed for doctor visits	2.100
Average cost of one missed working day to the employer	€205.00
Average loss of productivity of one missed working day to the economy	€306.80

27. May U. Selbstmedikation in Deutschland. Eine ökonomische und gesundheitspolitische Analyse. Wissenschaftliche Verlagsgesellschaft mbH Stuttgart (2002).
28. Federal Statistical Office, Germany (2002).
29. Federal Statistical Office, Germany (2002).

COUNTRY ANALYSES
ITALY

ITALY

In Italy, the total market volume was 1 544.4 million packs at end June 2003[30]. Out of these, 309.4 million packs corresponded to the non-prescription market. Of the total prescription market of 1 235 million packs, 913 million were reimbursable and 322 million not reimbursable. The assumption to shift 5% of the reimbursable prescription volume to self-medication would correspond to 45.7 million packs.

TABLE 1 (ITALY)

ITALY	
Pharmaceutical market up to end June 2003	**Packs (millions)**
Total pharmaceutical market:	1 554.404
Prescription, of which:	1 235.042
Reimbursable	913.027
Not reimbursable	322.015
Non-prescription, of which:	309.362
Not advertisable	76.337
Advertisable (= self-medication)	233.025
Substitution volume (5% of the reimbursable prescription market)	45.651

30. IMS Health, moving annual total (June 2003).

COUNTRY ANALYSES
ITALY

Table 2 (Italy) shows the impact of a shift of 45.7 million reimbursable packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(ITALY)

ITALY

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 5% equivalent to 45.651 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	34.324 million fewer doctor consultations	1 201.351
Treatment with medicines	Public funds	+	45.651 million fewer medicine packs	287.604
Patient co-payment	Public funds	-	45.651 million fewer co-payments	-16.434
Savings for public funds				**1 472.520**
Absence from work caused by treatment	Employers	+	4 290 540 fewer visits	135.152
Absence from work caused by illness	Employers National Economy	+	3 225 021 fewer working days	807.018
Savings for employers and national economy				**942.170**
Total annual savings				**2 414.690**

COUNTRY ANALYSES
ITALY

Freed up doctors' time: With an average estimated time of 10 minutes per consultation, time freed up as a result of the lower number of doctor visit for minor ailments would represent 7.6 million doctor working hours per annum or 22 hours per doctor per year.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (Italy). It should be noted that cost-sharing on medicines was reintroduced in Italy in 2002. The model of cost-sharing differs from region to region, and is a flat charge per reimbursed prescribed item. The average co-payment per reimbursed pack is estimated at €0.36 (to be applied to 100% of the market), thus accounting for 2.7% of public expenditure on medicinal products.

TABLE 3
(ITALY)

ITALY	
Statistical data	
Number of medical doctors	341 211
Average number of prescribed items per doctor visit [31]	1.33
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	34.324 17.162 4.291
Cost of a doctor visit	€35.00
Average price of a non-prescription medicine [32]	€6.30
Patient co-payment per prescribed item [33]	€0.36
Total population (2002) [34]	58 027 760
People in employment (36.24%) [35]	21 147 676
Total working days lost per annum due to illness lasting less than three days (12.2 hours/person/year) [36], of which an assumed 10% reduction represents	32 250 206 3 225 021
Avoided doctor visits during working hours	4 290 540
Social cost of a doctor visit (telephone, transport, loss of working time)	€31.50
Average cost of one missed working day to the employer [37]	€134.00
Average loss of productivity of one missed working day to the economy [38]	€250.00

31. Anifa (2003).
32. Anifa (2003.)
33. Ministry of Health (2002). In 2002, cost-sharing on prescribed medicines was reintroduced. The model of cost-sharing is different region to region and is a flat charge per reimbursed prescription. The average co-payment per reimbursed pack is calculated at €0.36 (to apply to 100% of the market).
34. Eurostat (2002).
35. Istituto Nazionale di Statistica (2003).
36. Confindustria (1996).
37. Istituto Nazionale di Statistica (2003).
38. Istituto Nazionale di Statistica (2003).

COUNTRY ANALYSES
PORTUGAL

PORTUGAL

The total market volume at end September 2003 was 249 147 956 packs[39]. Out of this number, 163 912 454 packs corresponded to reimbursable prescription products, 25 288 423 to non-reimbursable prescription products and 59 947 079 to non-prescription products. The substitution volume has been estimated to represent 5% of the reimbursable prescription market.

TABLE 1
(PORTUGAL)

PORTUGAL	
Pharmaceutical market up to end September 2003	**Packs (millions)**
Total pharmaceutical market	249.148
Prescription, of which: Reimbursable Not reimbursable	189.201 163.913 25.288
Non-prescription, of which: Reimbursed Not reimbursed	59.947 19.694 40.253
Substitution volume (5% of the reimbursable prescription market)	8.196

39. IMS Health, moving annual total (September 2003).

COUNTRY ANALYSES
PORTUGAL

Table 2 (Portugal) shows the impact of a shift of 8.2 million reimbursable prescription packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(PORTUGAL)

PORTUGAL

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 5% of the reimbursable prescription market equivalent to 8.196 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	3.610 million fewer doctor consultations	37.187
Treatment with medicines	Public funds	+	8.196 million fewer medicine packs	32.373
Patient co-payment	Public funds	-	8.196 million co-payments	-9.825
Savings for public funds				59.735
Absence from work caused by treatment	Employers	+	225 650 days	12.298
Absence from work caused by illness	Employers National Economy	+	710 094 days	77.626
Savings for employers and national economy				89.924
Total annual savings				149.659

COUNTRY ANALYSES
PORTUGAL

Freed up doctors' time: With an average estimated time of 10 minutes per consultation [40], time freed up as a result of the lower number of doctor visit for minor ailments would represent 602 000 doctor working hours per annum or 18 hours per doctor per year.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (Portugal).

TABLE 3
(PORTUGAL)

PORTUGAL	
Statistical data	
Number of medical doctors	34 246
Average number of prescribed items per doctor visit [41]	2.27
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	3.610 1.805 0.451
Cost of a doctor visit [42]	€10.30
Average price of a non-prescription medicine [43]	€3.95
Patient co-payment per prescribed item (30.35%) [44]	€1.20
Total population [45]	10 330 120
People in employment (49.1%) [46]	5 072 100
Total working days lost per annum due to illness lasting less than three days (1.4 days/person/year) [47], of which an assumed 10% reduction represents	7 100 940 710 094
Average time missed from work due to a doctor visit, of which it is assumed 25% is made during working hours	240 minutes
Avoided working days (of 8 hours) missed for doctor visits	225 650
Average cost of one missed working day to the employer [48]	€54.50
Average loss of productivity of one missed working day to the economy [49]	€109.32

40. IGIF Global Accounts (2000).
41. Infarmed (2002).
42. IGIF-SNS Contas (2000).
43. IMS Health.
44. Infarmed (2002).
45. Eurostat (2002).
46. Instituto Nacional de Estatística, Portugal. (2003, 3rd Q).
47. IIES (Statistic Department of Social Security).
48. IIES (Labour cost average per employee per day).
49. Instituto Nacional de Estatística Portugal (2001).

COUNTRY ANALYSES
SPAIN

SPAIN

In Spain the total market volume (EFP or advertisable non-prescription medicines not included) at the end of June 2003 was 965 243 699 packs[50]. Out of this number, 792 270 974 packs corresponded to reimbursable prescription products, 54 258 431 to non-reimbursable prescription products and 118 714 294 to non-advertisable non-prescription medicines (excluding EFPs). In order to define a potential OTC market, different groups that include EFP or OTC products have been taken into consideration. The substitution volume has been estimated as 15% of the reimbursable Rx segment of the potential OTC market, representing 43.203 million packs.

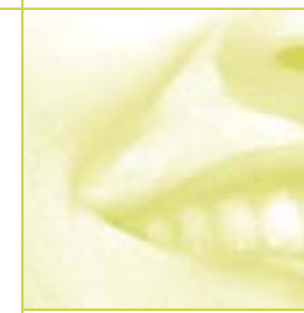
TABLE 1
(SPAIN)

SPAIN	
Pharmaceutical market up to end June 2003 (EFPs not included)	**Packs (millions)**
Total pharmaceutical market	965.244
Prescription, of which:	846.529
Reimbursable	792.271
Not reimbursable	54.258
Non-prescription not advertisable, of which:	118.714
Reimbursed	90.685
Not reimbursed	28.029

TABLE 1A
(SPAIN)

SPAIN	
Potential OTC market [51]	**Packs (millions)**
Potential OTC market	450.987
Prescription, of which:	332.273
Reimbursable	288.021
Not reimbursable	44.252
Non-prescription, of which:	118.714
Reimbursed	90.685
Not reimbursed	28.029
Substitution volume (15% of the reimbursable prescription market)	43.203

50. IMS Health, moving annual total (June 2003).
51. List of groups considered: Group A: vitamins and mineral supplements, appetite stimulants, antacids, antiflatulents, H2 antagonists and acid pump inhibitors, functional gastro-intestinal disorders, antiemetics and antinauseants, laxatives, antidiarrhoeals, antiobesity, other oral antidiabetics. Group B: plain iron and iron combination products. Group C: antivaricosis and antihaemorrhoidal preparations. Group D: acne, dermatological antifungals, emollients, anti-pruritic products, antipsoriasis products, topical viral infection products, topical corticosteroids, antiseptics and disinfectants. Group G: gynaecological antifungals, antiseptics other gynaecological products, hormonal contraceptives, other urological products. Group M: topical anti-rheumatics. Group N: local topical anaesthetics, analgesics non-narcotic, anti-migraine preparations. Group P: anthelmintics. Group R: topical and systemic nasal preparations, throat preparations, chest rubs and other inhalants, cough and cold preparations, systemic antihistamines. Group S: ophthalmological anti-infectives, preparations for the treatment of non-specific conjunctivitis, local anaesthetics, artificial tears and ocular lubricants, ophthalmological diagnostic agents, other ophthalmologicals, earwax removal products and other otologicals. Group V: all other therapeutic products.



COUNTRY ANALYSES
SPAIN

Table 2 (Spain) shows the impact of a shift of 43.2 million reimbursable prescription packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(SPAIN)

SPAIN

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 15% of the potential prescribed reimbursable OTC equivalent to 43.203 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	32.730 million fewer doctor consultations	567.532
Treatment with medicines	Public funds	+	43.203 million fewer medicine packs	284.276
Patient co-payment	Public funds	-	12.961 fewer co-payments (43.203 million x 30%)	-34.113
Savings for public funds				**817.695**
Absence from work caused by treatment	Employers	+	596 634 days	67.396
Absence from work caused by illness	Employers National Economy	+	1 377 000 days	322.126
Savings for employers and national economy				**389.521**
Total annual savings				**1 207.216**

COUNTRY ANALYSES
SPAIN

Freed up doctors' time: With an average time of 6.12 minutes per consultation[52], time freed up as a result of the lower number of doctor visit for minor ailments represents 3.3 million doctor working hours per annum or 22 hours per doctor per year.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (Spain).

TABLE 3
(SPAIN)

SPAIN	
Statistical data	
Number of medical doctors	150 230
Average number of prescribed items per doctor visit [53]	1.32
Number of doctor visits avoided per annum (millions)	32.730
Cost of a doctor visit [54]	€17.34
Average price of a non-prescription medicine [55]	€6.58
Patient co-payment per prescribed item 40% (70% of people are exempted [56]	€2.63
Total population [57]	41 837 894
People in employment (32.9%) [58]	13 770 000
Total working days lost per annum due to illness lasting less than three days (8 hours/person/year), of which an assumed 10% reduction represents	13 770 000 1 377 000
Average time missed from work due to a doctor visit,[59] of which it is assumed 25% is made during working hours	70 minutes
Avoided working days (of 8 hours) missed for doctor visits	596 634
Average cost of one missed working day to the employer [60]	€112.96
Average loss of productivity of one missed working day to the economy [61]	€233.93

52. Insalud (2000).
53. Ministerio de Sanidad y Consumo (2002) number of prescriptions in 2002 661.402.000, of which 74.2% are written by general practitioners (Source: IMS). Number of general practitioners: 44.549 (Source: Pharbase). Number of patients visits per day. 40 (Ipsos 1999 general physicians survey). Number of working hours in 2002: 1664.9 (208.1 days) Source: (Encuesta de coyuntura laboral).
54. Soikos (2003).
55. IMS Health (June 2003).
56. Insalud (2001).
57. Eurostat (2003).
58. INE. Encuesta sobre el tiempo de trabajo en España. 2000 total días de baja por enfermedad año trabajador (February 2003).
59. Ministerio de Sanidad y consumo. Encuesta nacional de salud de España (1997).
60. Ministerio de Sanidad y consumo. Encuesta nacional de salud de España (1997).
61. Instituto Nacional de Estadística. Contabilidad Nacional de España (2002).

COUNTRY ANALYSIS SWITZERLAND

SWITZERLAND

The Swiss model is based on the assumption that 5% of the volume of reimbursed medications (made up of prescription and non-prescription medicines) is being shifted to self-medication. Data for 2003[1] (see Table 1 (Switzerland)) show that the total reimbursed market was 84.895 million packs. A 5% volume shift to self-medication would therefore correspond to 4.249 million packs.

TABLE 1
(SWITZERLAND)

SWITZERLAND	
Pharmaceutical market in 2003	**Packs**
Total pharmaceutical market	164 706 434
Prescription, of which: Reimbursable Not reimbursable	64 347 025 57 663 201 6 683 824
Non-prescription, of which: Reimbursable Not reimbursable	100 359 409 27 321 547 73 037 862
Total reimbursed market	84 984 748
Substitution volume (5% of the reimbursable market)	4 249 237

1. IMS Health (2003).

COUNTRY ANALYSIS SWITZERLAND

Table 2 (Switzerland) shows the impact of a shift of 4.2 million reimbursable packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2 (SWITZERLAND)

SWITZERLAND

Impact on public funds and the economy of a volume shift of prescribed items to self-medication

(Substitution volume = 5% equivalent to 4.249 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	2.544 million fewer doctor consultations	180.981
Treatment with medicines	Public funds	+	4.249 million fewer medicine packs	37.615
Patient co-payment	Public funds	-	4.249 million fewer co-payments	-5.642
Savings for public funds				212.954
Absence from work caused by treatment	Employers	+	59 616 fewer working days	10.815
Absence from work caused by illness	Employers National Economy	+	420 000 fewer working days	182.854
Savings for employers and national economy				193.669
Total annual savings				406.623

COUNTRY ANALYSIS
Switzerland

Freed up doctors' time: With an average estimated time of 12 minutes per consultation, time freed up as a result of the lower number of doctor visit for minor ailments would represent 508 723 doctor working hours per annum.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (Switzerland).

TABLE 3
(SWITZERLAND)

SWITZERLAND	
Statistical data	
Number of medical doctors[2]	18 315
Average number of prescribed items per doctor visit[3]	1.67
Number of doctor visits avoided per annum (millions) of which 50% by the active population, of which 25% made during working hours	2.544 1.272 318
Cost of a doctor visit	€71.15
Average price of a non-prescription medicine[4]	€8.85
Patient co-payment per prescribed item[5] (15%)	€1.33
Total population (2002)[6]	7 200 000
People in employment (40%)[7]	3 500 000
Total working days lost per annum due to illness lasting less than three days (9,6 hours/person/year), of which an assumed 10% reduction represents	4 200 000 420 000
Avoided working days (of 8 hours) missed for doctor visits	59 616
Average cost of one missed working day to the employer[8]	€181.40
Average loss of productivity of one missed working day to the economy[9]	€435.37

2. IHA/Gfk (2004).
3. IMS (2003) Swiss Diagnose Index (SDI) IHA-IMS Switzerland (2003).
4. IMS (2003).
5. KOBE-Anteil.
6. IHA/Gfk Vademecum (2004).
7. Department of statistics, SUVA, Stefan Scholz-Odermatt (April 2004).
8. Christoph Lieb, ECOPLAN (May 2004).
9. Department of statistics, SUVA, Stefan Scholz-Odermatt (April 2004).

COUNTRY ANALYSES
UNITED KINGDOM

UNITED KINGDOM

The total prescribed market in the United Kingdom in the 12 months up to June 2003 was 913.651 million packs[62]. Out of this number, 769.429 million packs corresponded to prescribed prescription products and 144.222 million to prescribed non-prescription medicines.

The total self-medication market excluding sales through the chains Boots and Superdrug represented 116.693 million packs. The UK model is based on the assumption that 5% of the prescribed pre-scription volume is shifted to self-medication, corresponding to 38.471 million packs.

TABLE 1
(UNITED KINGDOM)

UNITED KINGDOM	
Pharmaceutical market up to end June 2003	**Packs (millions)**
Total pharmaceutical market	1 338.778
Total prescribed market	913.652
Prescription	769.430
Non-prescription, of which:	569.348
Prescribed	144.222
Self-medication	425.126
Substitution volume (5% of the prescription market)	38.471

62. IMS Health, moving annual total (June 2003).

COUNTRY ANALYSES
UNITED KINGDON

Table 2 (United Kingdom) shows the impact of a shift of 38.5 million prescribed Rx packs to self-medication and the related possible savings for public funds, employers and the national economy.

TABLE 2
(UNITED KINGDOM)

UNITED KINGDOM

Impact on public funds and the economy of a volume shift of prescribed items to self-medication
(Substitution volume = 5% of the prescribed Rx market equivalent to 38.471 million packs)

Type of impact	Affected party		Units	Impact (euro millions)
Treatment by doctor	Public funds	+	21.138 million fewer doctor consultations	453.414
Treatment with medicines	Public funds	+	38.471 million fewer medicine packs	215.056
Patient co-payment	Public funds	-	5.001 million fewer co-payments	-45.012
Savings for public funds				623.458
Absence from work caused by treatment	Employers	+	1 321 136 days	132.114
Absence from work caused by illness	Employers National Economy	+	2 448 200 days	626.691
Savings for employers and national economy				758.805
Total annual savings				1 382.263

COUNTRY ANALYSES
UNITED KINGDON

Freed up doctors' time: With an average time of 8 minutes per consultation[63], time freed up as a result of the lower number of doctor visit for minor ailments represents 2.8 million doctor working hours per annum or 21 hours per doctor per year.

The statistical data to evaluate the impact of this 5% volume shift and their sources are set out in Table 3 (United Kingdom).

TABLE 3
(UNITED KINGDOM)

UNITED KINGDOM	
Statistical data	
Number of medical doctors	136 800
Average number of prescribed items per doctor visit [64]	1.82
Number of doctor visits avoided per annum (millions), of which 50% by the active population, of which 25% made during working hours	21.138 10.569 2.642
Cost of a doctor visit[65]	€21.45
Average price of a non-prescription medicine [66]	€5.59
Patient co-payment per prescribed item (87% of prescriptions for 50% of the population are exempted) [67]	€9.00
Total population [68]	60 109 410
People in employment (40.73%) [69]	24 482 000
Total working days due to sickness in 2002 [70], Total working days lost per annum due to minor illness (1 working day/person/year) of which an assumed 10% reduction represents (days)	166 000 000 24 482 000 2 448 200
Average time missed from work due to a doctor visit [71]	240 minutes
Avoided working days (of 8 hours) missed for doctor visits	1 321 136
Average cost of one missed working day to the employer [72]	€100.00
Average loss of productivity of one missed working day to the economy [73]	€255.98

63. Proprietary Association of Great Britain (PAGB) (2003).
64. IMS Health moving annual total (June 2003).
65. Proprietary Association of Great Britain (PAGB) (2003).
66. IMS Health moving annual total (June 2003).
67. Proprietary Association of Great Britain (PAGB) (2003).
68. Eurostat (2003).
69. UK National Statistics (Oct-Dec 2003).
70. Confederation of the British Industry report "The Lost Billions" (May 2003).
71. Proprietary Association of Great Britain (PAGB) (2003).
72. Confederation of the British Industry report "The Lost Billions" (May 2003).
73. UK National Statistics (2003).

PROJECTION IN AN ENLARGED EUROPE

The potential savings in the rest of the European Union can be estimated using the results obtained from the analysis in the countries examined in this study. The analysis for all EU Member States after enlargement is based on the average savings per head of the population of the seven countries studied. In practice of course, there will be considerable variation across the EU keeping in mind the extrapolation method used.

TABLE 1A

COMPILATION TABLE 1A

Annual savings in an enlarged Europe

	Austria	France	Germany	Italy	Portugal
Population (millions)	8.1	61.2	82.3	58.0	10.3
Annual savings for public funds (euro millions)	137.9	1 458.0	2 454.3	1 472.5	59.7
Per head of population (€)	16.96	23.81	29.83	25.38	5.78
Annual savings for national economy (euro millions)	92.4	1 024.2	1 197.5	942.2	89.9
Per head of population (€)	11.36	16.73	14.55	16.24	8.70
Total annual savings (euro millions)	**230.3**	**2 482.2**	**3 651.8**	**2 414.7**	**149.6**
Per head of population (€)	**28.32**	**40.54**	**44.38**	**41.61**	**14.48**

PROJECTION
IN AN ENLARGED EUROPE

TABLE 1B

COMPILATION TABLE 1B

Annual savings in an enlarged Europe

	Spain	United Kingdom	Total of 7	Other 18 EU Member States	European Union of 25 Member States
Population (millions)	41.8	60.1	321.9	135.7	457.7
Annual savings for public funds (euro millions)	817.7	623.5	7 023.6	2 961.2	9 984.8
Per head of population (€)	19.54	10.37	21.82	21.82	21.82
Annual savings for national economy (euro millions)	389.5	758.8	4 494.5	1 894.9	6 389.4
Per head of population (€)	9.31	12.62	13.96	13.96	13.96
Total annual savings (euro millions)	**1 207.2**	**1 382.3**	**11 518.1**	**4 856.2**	**16 374.3**
Per head of population (€)	**28.85**	**23.00**	**35.78**	**35.78**	**35.78**

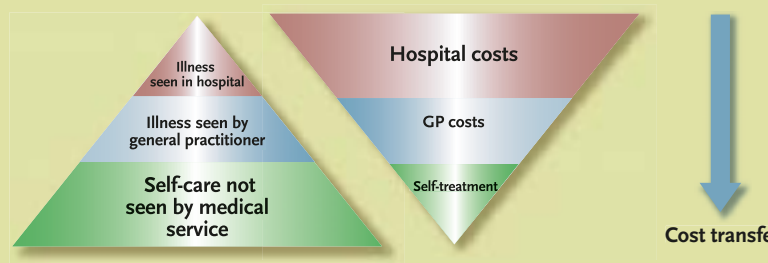
SUMMARY

In the seven countries studied, total savings to public funds and to the national economies from a shift of prescribed items to responsible self-medication amount to just over 11.5 billion euros. The figures from the countries studied, when added to the rest of the enlarged Europe figures, produce a potential pan-European economic savings effect valued at 16.4 billion euros.

Evidence shows that the most common and inexpensive form of care is self-care and the most expensive forms of care are secondary and tertiary care. On the other hand, encouraging a shift from secondary to primary to self-care would have the effect of transferring costs through each level. The maximum benefit of more self-care would be gained by a reduction in costs in the secondary and primary care sectors without at the same time transferring a substantial financial burden upon the individual. This model of comparison between illness seen and costs incurred (see Figure 3) is widely accepted in considerations around the economics of healthcare.

FIGURE 3

ILLNESS SEEN VERSUS COSTS INCURRED



In order to realise the full benefits of such as cost transfer, a number of recommendations are set out in Part III of this study.

PART II:

RX-TO-OTC SWITCHING AND NEW INDICATIONS FOR SELF-MEDICATION IMPACT ON PUBLIC HEALTH

INTRODUCTION

Responsible self-medication is nowadays widely recognised as an important part of healthcare systems. This is documented by numerous policy statements, and two examples of those are the following:

"It has become widely accepted that self-medication has an important place in the healthcare system. Recognition of the responsibility of individuals for their own health and awareness that professional care for minor ailments is often unnecessary have contributed to this view. Improvements in people's general knowledge, level of education and socioeconomic status in many countries form a reasonable basis for successful self-medication. New drugs with specific pharmacological action, such as histamine H2-receptor antagonists, nonsteroidal anti-inflammatory compounds (NSAID) and nicotine preparations for cessation of smoking, have been successfully reclassified from prescription to non-prescription status in many countries."

WHO, Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-Medication, Geneva 2000[1]

"Developing the competitiveness of the non-prescription market, with due consideration to issues of safety and affordability to patients, can bring significant benefits to governments and to consumers as well as to industry itself. Although the costs of the medicines are transferred to the consumer, they gain in terms of greater accessibility to the medicines, without the need for a medical consultation beforehand. Accordingly, there are significant time savings to both the consumer and the health professional."

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions
A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, 1 July 2003[2]

Switching medicines from prescription to non-prescription status is an important element in the innovation of responsible self-medication. Products moved to non-prescription status in the past have been able to prove their contribution to public health. Offering a wider range of non-prescription medicines is in line with people's desire to take an active role in the management of their own health.

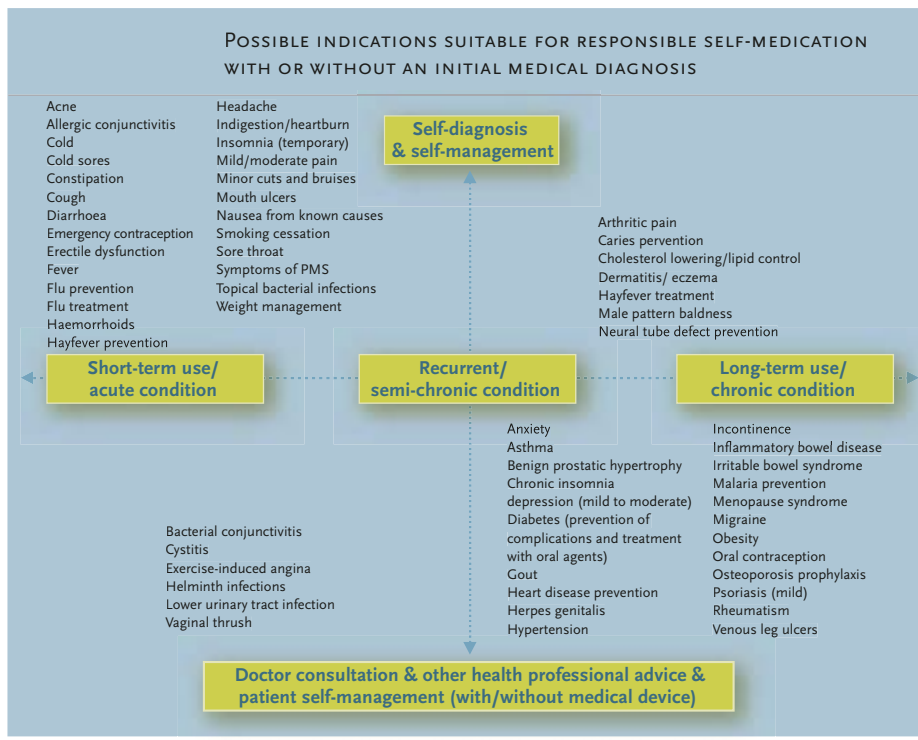
1. http://www.who.int/medicines/library/qsm/who-edm-qsm-2000-1/who-edm-qsm-00_1.shtml/ http://whqlibdoc.who.int/hq/2000/WHO_EDM_QSM_00.1.pdf

2. http://pharmacos.eudra.org/F3/g10/docs/G10_CommComm_EN.pdf

INTRODUCTION

The debate on a larger range of new indications suitable for self-treatment is in full swing. Based on considerations around collaborative care (in which the doctor makes the first diagnosis and may write a prescription but where further episodes are treated by the patients themselves), AESGP analysed the information needs to deliver collaborative care in the best possible way in a research project carried out for the European Commission's Directorate-General Health and Consumer Protection. This project considered potential indications for non-prescription medicines (see Figure 4).

FIGURE 4



Source: AESGP study on new indications and related information needs carried out for the European Commission's Directorate-General Health and Consumer Protection, January 2002 [3].

The following three case studies demonstrate the public health value of new self-medication indications.

3. "Development of an information policy for medicinal products", January 2002, available on http://www.aesgp.be/ResearchProject/FinalReport.pdf

CASE STUDY I
VAGINAL MYCOSIS

The active substance clotrimazole was launched by Bayer Healthcare in 1973 under the name Canesten® as the first of the "azole" antifungal class of medicines. In 1992, clotrimazole was switched from prescription to non-prescription status in the United Kingdom, and was subsequently given non-prescription status in many other countries around the world for the treatment of external mycosis. Germany moved the vaginal use of clotrimazole in a gynaecological 3-day and 1-day treatment regimen to non-prescription use in 1994. The 6-day gynaecological treatment remained prescription only.

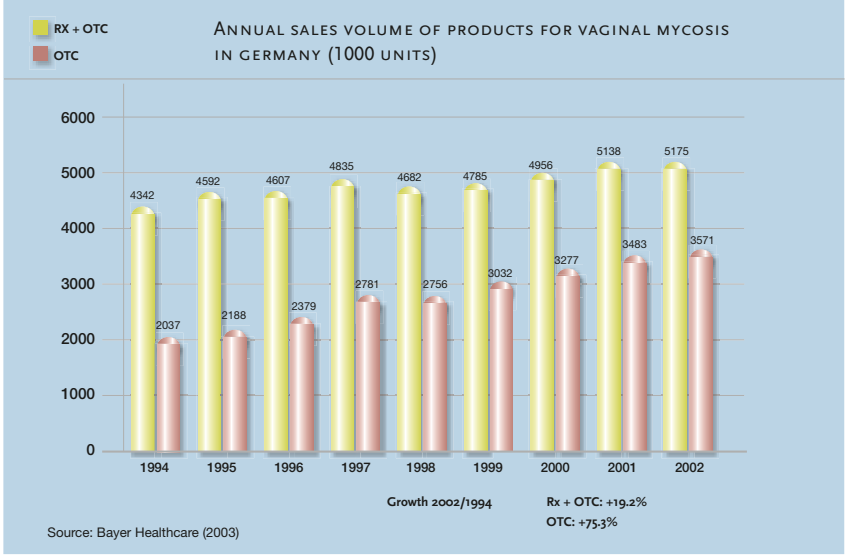
The overall experience with the availability of clotrimazole for vaginal thrush indicates that patients benefited because they could obtain an effective treatment more quickly and conveniently without having to visit a doctor. Vaginal yeast infections occur frequently and most women do not require medical intervention to make the diagnosis. The move to non-prescription status has made patients more aware of the availability of such treatments and promoted the patient's responsibility for her own health and treatment. It has decreased costs to social security schemes and social costs by eliminating the need to visit the doctor.

In this context, the pharmacist has the possibility to provide important guidance and information services. As most patients respond to treatment, side-effects are infrequent and compliance is high, it is an area where the pharmacist is able to make an important contribution to public health provided the communication takes into account the sensitivity of many patients. The pharmacist may exercise a gatekeeper role and may refer the patient to a doctor in case of first-time sufferers, pregnancy, repeat attacks, patients under 16 years of age or more serious symptoms such as vaginal bleeding, ulcers or abdominal pain.

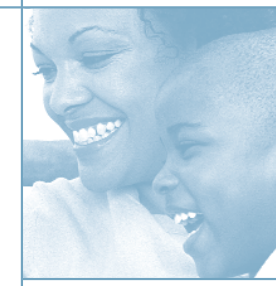
CASE STUDY 1
VAGINAL MYCOSIS

Since the moment clotrimazole became available for vaginal use without a prescription, there have been no reports of adverse reactions due to misuse of vaginal antifungal preparations. Concerns expressed when the ingredient was first switched to non-prescription status that the promotion of such products directly to the consumer would unnecessarily increase consumption have also not been substantiated. As a result of the switch, the non-prescription use has evidently increased (see Figure 1 (Vaginal mycosis)), but the level of self-medication for Canesten Gyn® - the leading product containing clotrimazole for vaginal use - has reached a ceiling, as shown in Figure 2.

FIGURE 1
(VAGINAL MYCOSIS)



CASE STUDY I
VAGINAL MYCOSIS



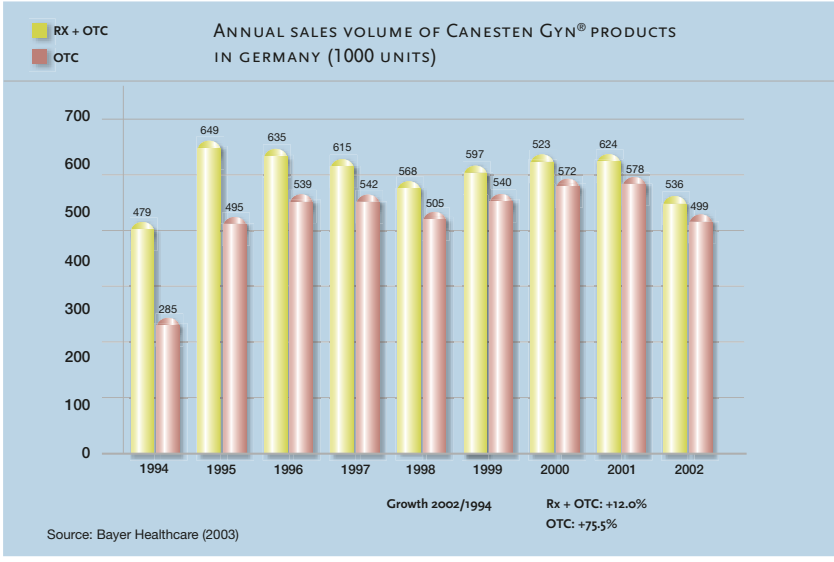


FIGURE 2
(VAGINAL MYCOSIS)

The level of prescription use has been reduced, but a considerable amount is still prescribed or doctor-driven self-medication. This is partially due to the fact that products containing clotrimazole were still reimbursed and patients change behaviour only slowly. Many consumers still feel compelled to get a recommendation from a doctor while others are simply unaware that products to treat their condition are also available without a prescription.
A third group of patients felt they were entitled to reimbursement, which led them to visit the doctor.

With the switch from prescription to non-prescription status, new packs and patient information leaflets were provided by manufacturers to educate patients about their infection, causes, product usage and to provide advice on how to prevent future vaginal yeast infection occurrences. Brochures and public relation activities also helped to inform patients about self-medication and self-care.

CASE STUDY 1
VAGINAL MYCOSIS

Until now, very few brands have placed advertisements in traditional media. Table 1 illustrates the self-medication share for some products in this indication.

TABLE 1
(VAGINAL MYCOSIS)

VAGINAL MYCOSIS

Share of self-medication in relation to the total volume for a number of products in this category in Germany (2002)

Canesten Gyn	79
Kadefungin	33
Canifug	24
Fungizid	51
Antifungol	50
Mykofungin	42

Source: Bayer Healthcare

A number of companies visit gynaecologists and encourage them to continue prescribing their products, which evidently influences the share of self-medication as reflected in Table 1.

Based on a self-medication level of 45% (1.6 million packs) in vaginal mycosis out of a total of 3.6 million packs sold on the German market in 2002, the savings for public funds, employers and the national economy from these 45% are shown in Table 2.

TABLE 2
(VAGINAL MYCOSIS)

VAGINAL MYCOSIS

Impact on public funds and the economy from self medication versus prescription in vaginal mycosis in Germany (2002) (euro millions)

	All products used in self-medication	Canesten® only used in self-medication
Savings for public funds	38.8	10.7
Savings for employers and the national economy	26.7	7.0
Total savings	65.5	17.7

CASE STUDY 1

VAGINAL MYCOSIS

The situation is however changing in Germany due to the impact of the 2003 healthcare reform, which came into force on 1 January 2004. Most non-prescription medicines in Germany are no longer reimbursable and doctor visits will cost €10 per quarter. This is expected to encourage patients to consult the pharmacy as their first port of call for medication rather than taking the longer and more expensive route via the medical doctor. Vaginal yeast infection products such as Canesten® Gyn will certainly be one area where patients will reassess their options.

Some argue that a switch from prescription to non-prescription (Rx to OTC) status automatically brings higher prices, but this is not true. Today there are generic options in prescription and non-prescription use with recent developments indicating an increasing market share for generics in both sectors. This allows for a large price range, indicating that normal market conditions exist.

In summary, the switch of vaginal mycosis medications from prescription to non-prescription has been beneficial to the stakeholders – and particularly to the public healthcare budgets and patients – as wider availability has increased the number of treatments without increasing the expenses for the social security system. They are safe, have not been over consumed, and are a good example for a segment of medications which can safely be moved to self-medication.

CASE STUDY II
SMOKING CESSATION

Nowadays, the need to adopt an active approach to smoking cessation is well recognised. Scientific evidence has shown conclusively that all forms of tobacco use cause health problems throughout life, frequently resulting in death or disability. Besides, smoking-related diseases and deaths represent a huge drain on national resources.

Nicotine patches for smoking cessation were first marketed without a prescription in 1992, although nicotine gum had already been available as a non-prescription (OTC) medicine in some countries since the early eighties. Since then, smoking cessation has been a growing OTC category as the negative impact of smoking on health has increasingly become recognised, both by consumers and by governments.

TOBACCO CONSUMPTION IN THE EUROPEAN REGION [4]

In 2001, approximately 30% of the adult population of the European Region were regular smokers. While smoking prevalence has fallen from 45% to 30% (38% for men and 24% for women) over the past 30 years and is currently stable, it is still unacceptable in terms of public health.

Prevalence among people between 15 and 18 year of age is about 30%, with no decrease in the preceding four years in Western Europe and a slight increase in Eastern Europe. People from lower socioeconomic groups still smoke significantly more than the average adult population, and there is no sign of this difference being reduced.

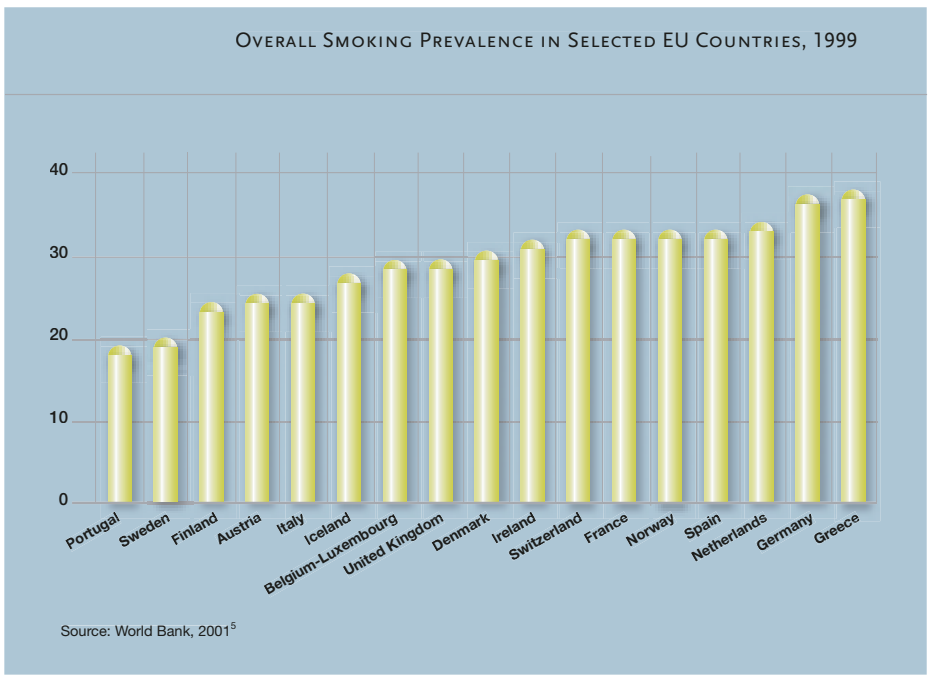
The European Region of the World Health Organization (WHO), with only 15% of the world's population, faces nearly one third of the worldwide burden of tobacco-related diseases. Each day, nearly 3 400 people in the European Region die from tobacco-related causes. Tobacco products are responsible for 1.2 million deaths (or 14% of all deaths) in Europe each year, and unless more effective measures are implemented they will cause 2 million deaths (20% of all deaths) each year by 2020.

Smoking prevalence remains at a level that is devastating for public health and future generations. The negative trend among young people, women and lower socioeconomic groups are of particular concern.

4. Tobacco control in the WHO European Region: Current status and developments. Fact sheet 06/02. Copenhagen, 17 September 2002.

CASE STUDY II
SMOKING CESSATION

TABLE 1
(SMOKING CESSATION)

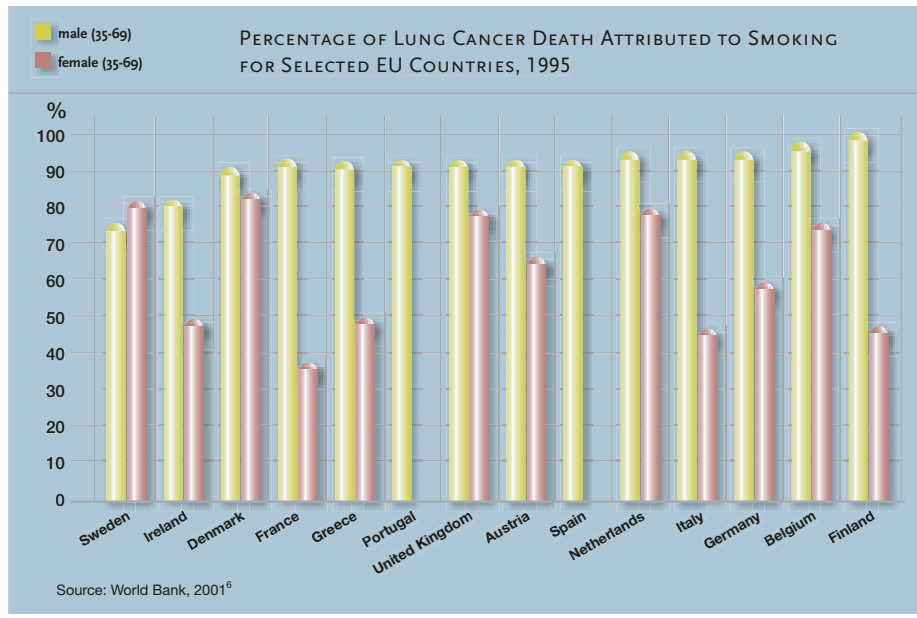


In all EU countries, smoking has proved to be a major cause of lung cancer and other diseases.

5. The World Bank Group. Regional Report Europe. Economics of Tobacco for the Europe (EU) Region. June 24, 2001.

TABLE 2
(SMOKING CESSATION)

CASE STUDY II
SMOKING CESSATION



HEALTH AND ECONOMIC CONSEQUENCES OF SMOKING (HECOS MODEL)

The HECOS model, developed as part of the 1999-2001 WHO European Partnership Project to Reduce Tobacco Dependence, predicts the health and economic consequences of smoking over the next 20 years. The key purpose of this model is to demonstrate the beneficial effect of smoking cessation, both in terms of health gains and cost-effectiveness. The model combines, for each country, epidemiological data (population size, smoking prevalence, smoking-related diseases and mortality rates) and an estimate of the direct healthcare costs associated with tobacco consumption.

MORBIDITY CASES IN A SELECTED NUMBER OF COUNTRIES

Smoking is a major preventable cause of increased morbidity and mortality. It is the primary cause in approximately 85% of all cases of lung cancer, 85% of all chronic obstructive pulmonary diseases and 35% of myocardial infarctions[7]. The World Health Organization has estimated that 1 in 4 smokers die as a result of smoking-related diseases. Thus, the importance of smoking as a major risk factor for morbidity and mortality cannot be underestimated.

Table 3 shows the predicted change in the number of cases of smoking-related disease in 20 years in a selected number of countries. The figures show the additional cases of disease that are directly caused by smoking.

6. The World Bank Group. Regional Report Europe. Economics of Tobacco for the Europe (EU) Region. June 24, 2001.
7. Fielding JE. Smoking: health effects and control. New England Journal of Medicine 313: 491-498, 1985.

CASE STUDY II
SMOKING CESSATION

TABLE 3
(SMOKING CESSATION)

SMOKING CESSATION					
Morbidity cases [8]					
	France	**Germany**	**Italy**	**Spain**	**UK**
# of COPD cases	1 419 727	1 729 202	1 657 081	2 652 724	1 194 405
# of Asthma exacerbations	394 178	662 028	342 360	663 468	768 064
# of CHD cases	247 736	1 480 015	370 411	199 276	2 689 084
# of Stroke cases	141 912	683 043	264 873	161 423	310 147
# of Lung cancer cases	53 948	57 886	63 805	31 680	58 679
# of Low birth-weight infants	245 128	283 562	216 391	48 110	49 453
Cumulative deaths	1 102 521	4 977 420	1 386 429	1 127 878	2 965 233

8. HECOS MODEL.

CASE STUDY II

SMOKING CESSATION

IMPROVED OUTCOMES IN A SELECTED NUMBER OF COUNTRIES

Smoking cessation interventions result in health gains, which in the long-term reduce the cost of healthcare for smoking-related diseases, releasing resources for other health care programmes. Table 4 shows the number of cases of smoking-related diseases and deaths prevented by a selected smoking cessation strategy [9].

TABLE 4
(SMOKING CESSATION)

SMOKING CESSATION

	France	Germany	Italy	Spain	UK
COPD cases averted	7 325	9 343	8 595	14 942	3 987
Asthma exacerbations averted	2 285	3 666	1 861	5 525	3 854
CHD cases averted	4 386	24 179	3 713	3 248	35 440
Stroke cases averted	3 321	16 253	5 379	2 789	6 168
Lung cancer cases averted	4 612	6 178	5 303	6 310	8 751
Low birth weight infants averted	3 386	4 038	2 986	773	775
Deaths averted	14 940	52 713	18 073	17 120	40 271
Life years averted	147 812	549 676	179 706	159 868	401 348

9. For all the countries, the smoking cessation strategy assumed is: 30% of smokers attempting to quit, with 75% of those using pharmacological therapy (efficacy estimated at 20%); 10 % using GP advice (efficacy estimated at 3.1%); and 15% using willpower (efficacy estimated at 1%).

CASE STUDY II

SMOKING CESSATION

MAJOR HEALTH BENEFITS OF SMOKING CESSATION

According to a Report of the Surgeon General[10], the health consequences of smoking cessation for those who quit smoking in comparison with those who continue to smoke are several and very important, among which:

- Smoking cessation has major and immediate health benefits for men and women of all ages. Benefits apply to persons with and without smoking-related diseases.
- Former smokers live longer than continuing smokers. Smoking cessation at all ages reduces the risk of premature death
- Smoking cessation decreases the risk of lung cancer, other cancers, heart attack, stroke and chronic lung disease.
- Former smokers have better health status than current smokers as measured in a variety of ways, including days of illness, number of health complaints and self-reported health status.

TABLE 5
(SMOKING CESSATION)

SMOKING CESSATION [11]

Smoking related disease	Impact of stopping smoking
Stroke	Reduced to that of non-smoker after 15 years
Cancers of mouth, throat, oesophagus	Risk halved 5 years after stopping
Coronary Heart Disease	Excess risk halved compared to continuing smoker within 1 year
Chronic Obstructive Pulmonary Disease	Slows decline in lung function
Lung cancer	Risk reduced by up to a half compared to continuing smoker after 10 years
Peptic Ulcer	Risk reduced after stopping
Peripheral vascular disease	Risk reduced after stopping

NICOTINE REPLACEMENT THERAPY

Nicotine is by far the most potent behaviourally active compound present in tobacco smoke, and there is considerable evidence to suggest that most people who smoke tobacco do so in order to experience its pleasant psychopharmacological properties[12].

There is also good evidence to suggest that a significant proportion of habitual smokers become addicted to nicotine. As a result, preparations containing pure nicotine have found a valuable place in the treatment of the withdrawal effects often experienced by habitual smokers during the early stages of abstinence[13]. Nowadays, nicotine replacement therapy (NRT) is available for self-medication in almost all European Countries.

10. United Kingdom. A Report of the Surgeon General (1990). The health benefits of smoking cessation.
11. Jackson G et al. Smoking cessation: a consensus statement with special reference to primary care. Int J Clin Pract 2001 55:385-392.
12. Balfour DJK. Nicotine and tobacco smoking habit. In Balfour DJK (Ed.) Psychotropic drugs of abuse-Section 130 of the International Encyclopedia of Pharmacology and Therapeutics, pp. 453-481, Pergamon Press, New York, USA, 1990.
13. Russell MAH. Nicotine replacement: the role of blood nicotine levels, their rate of change and nicotine tolerance. Progress in Clinical and Biological Research 261: 63-94, 1988.

CASE STUDY II
SMOKING CESSATION

Table 6 shows the results from the Cochrane review of NRT trials [14] available up to April 2000.

TABLE 6
(SMOKING CESSATION)

SMOKING CESSATION

Results from a nicotine replacement therapy meta-analysis

		Patients stopped smoking at 6-12 months				
		NRT		Placebo		
Type of NRT	Number of trials	Number/total	Percent	Number/total	Percent	NNT[15] (95% CI)
All trials						
Gum	48	1453/7387	20	1084/9319	12	12 (11 to 14)
Patch	31	1384/9708	14	495/5969	8	17 (14 to 20)
Intranasal spray	4	107/448	24	52/439	12	8 (6 to 14)
Inhaler	4	84/490	14	44/486	8	12 (8 to 26)
Sunlingual tablet	2	49/243	20	31/245	13	13 (7 to 103)

Nicotine replacement therapy (NRT) has been extensively tested in controlled clinical trials during the past 20 years and has been shown to reduce craving and tobacco withdrawal symptoms. The meta-analysis performed by the Cochrane Tobacco Addiction Group concluded that NRT doubles successful quit rates compared to placebo. Moreover, evidence-based clinical guidelines state that, except in special circumstances, NRT should routinely be used by smokers attempting to quit smoking [16]. As the majority of regular smokers are tobacco dependent, they should use NRT during their attempts to quit.

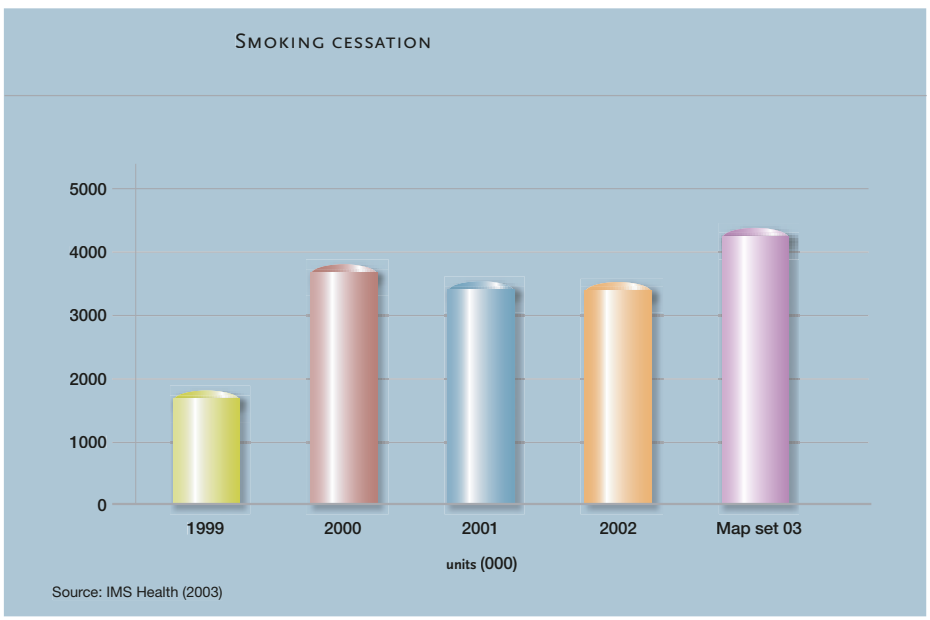
One of the most promising recent strategies to reduce smoking prevalence has been to increase the availability of proven safe and effective treatment for tobacco dependence. It is estimated that increased access to NRT in the United States has resulted in a 10-25% increase in the number of smokers who have quit smoking [17]. Thus, widening the availability of smoking cessation treatments will encourage more cessation attempts and therefore will increase success rates.

14. C Silagy et al. Nicotine replacement therapy for smoking cessation. (Cochrane Review). In: The Cochrane Li-brary, Issue 1, 2001. Chichester, UK
15. NNT (number needed to treat) is a measure of effectiveness. The NNT can be calculated by the following formula: NNT = 1/((IMPact/TOTact)-(IMPcon/TOTcon)), where IMPact is the number of patients given active treatment achieving the target, TOTact is the total number of patients given the active treatment, IMPcon is the number of patients given a control treatment achieving the target (placebo in this case) and TOTcon is the number of patients given the control treatment.
16. The Agency for Health Care Policy and Research. Smoking cessation clinical practice guideline. JAMA 1996; 275: 1270-80. Raw M, McNeill A, West R. Smoking cessation guidelines for health professionals. Thorax 1998, 53 (suppl 5), 11-12
17. Shiffman S, Gitchell J, Pinney JM et al. Public health benefit of over-the-counter nicotine medications. Tobacco Control 1997; 6:306-310

CASE STUDY II
SMOKING CESSATION

Table 7 shows how the use of NRT in France developed after the switch to non-prescription status in 2000.

TABLE 7
(SMOKING CESSATION)



Source: IMS Health (2003)

CASE STUDY III
HEART DISEASE PREVENTION

INTRODUCTION

It is estimated that one-third of total global deaths result from the various forms of cardiovascular disease. Significantly, coronary heart disease (CHD) is the leading cause of death in men over 45 years and women over 65 years throughout Europe[18], many of which could have been prevented by reducing risk factors such as high blood pressure, high cholesterol levels, obesity, physical inactivity and smoking. Nowadays, CHD prevention is the main challenge facing European healthcare systems as the disease is to a great extent responsible for increasing the cost of healthcare in the European economies.

Those who have already had a cardiovascular event are at high risk of recurrence and death. Nevertheless, this risk can be substantially lowered by introducing behavioural changes in life style and with a combination of medicines: statins for cholesterol lowering, anti-hypertensives against high blood pressure and acetylsalicylic acid.

ECONOMIC COSTS

Coronary heart disease is not only the single most common cause of death in the majority of European countries, it is also very costly, imposing a huge annual burden on the economy. Besides the costs of healthcare, the majority of CHD costs fall outside this area and are related to illness and death in those of working age. Looking only at the direct costs of CHD to the healthcare system therefore grossly underestimates the total impact of CHD. Production losses from death and illness in those of working age contribute to the overall financial burden. CHD not only has major economic consequences, it also has a human cost.

CHD PREVENTION

The need for a preventive approach to CHD is well recognised. Prevention of CHD aims to reduce events such as heart attacks and mortality and increase quality and duration of life. The priorities are to reduce recurrent illness (secondary prevention after a first coronary event) and to prevent CHD developing in healthy people with a high risk (primary prevention). Increasing awareness of the central role of primary prevention has great importance because only the creation of a genuine culture of prevention will in fact result in a further appreciable reduction in CHD. Prevention has become the fundamental aim once “at risk” subjects have been identified.

There has been a shift from assessing individual risk factors such us smoking or hypertension towards an assessment of the absolute risk based on a multifactor analysis of all relevant risk factors. Integrated assessment of the risk is important because many modest risk factors together can be worse than one very high risk factor alone.

18. European Cardiovascular disease statistics. 2000 edition. Compiled by Mike Rayner and Sophie Petersen. British Heart Foundation Health Promotion Research Group. Department of Public Health University of Oxford.

CASE STUDY III

HEART DISEASE PREVENTION

The European Society of Cardiology, the European Society of Hypertension, and the European Atherosclerosis Society have prepared coronary risk charts which, on the basis of the presence of diabetes, dyslipidaemia, arterial hypertension, attitude to smoking, sex and age, make it possible to establish the absolute risk of a coronary event at 10 years for each subject with no history of cardiovascular events. The graphic representation of the risk charts, which was created using the US Framingham Heart Study [19] (50 years study of 5.300 men and women) and the ease with which they can be used, make them a valuable tool for health professionals.

TABLE 1
(HEART DISEASE PREVENTION)

CHD PREVENTION

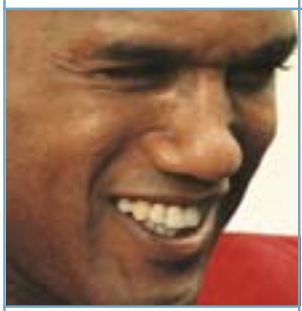
Proportion of UK population 35 - 69 with a predicted risk factor of 15%, 30% and 15-30%, with serum total cholesterol level >5.5mmol/l.

Risk level	Men	Women	Total	UK population (million)
15%	26.9%	8.6%	19.6%	4.9
30%	5.7%	0.4%	3.4%	0.9
15% - 30%	21.2%	8.2%	16.2%	4.0

Source: The Framingham Heart Study [20]

Nowadays there is consensus that there is a clear benefit to primary prevention for people who present a risk level of more than 15% to develop a coronary event at 10 years. This would mean that a substantial proportion of the population becomes eligible for treatment in the framework of a risk-reduction strategy.

19. The Framingham Heart Study is a health research project created in 1948 under the direction of the National Heart, Lung, and Blood Institute; NHLBI (USA). The objective of the Framingham Heart Study was to identify the common factors or characteristics that contribute to CVD by following its development over a long period of time in a large group of participants (using the population of Framingham, Massachusetts) who had not yet developed overt symptoms of CVD or suffered a heart attack or stroke.
20. Haq IU et al, Clinical Science 1996; 91: 399-413. Key Population & Vital Statistics. The Stationary Office. United Kingdom (1999).



CASE STUDY III

HEART DISEASE PREVENTION

MEASURES FOR PREVENTIVE TREATMENT

CHD risk can be significantly reduced by behavioural changes in lifestyle such as smoking cessation, exercise, healthy diet and with the use of medication such as acetylsalicylic acid, anti-hypertensives and cholesterol-lowering medicines.

In this context special mention has to be made of an Italian initiative named CardioLab [21], whose aim was to extend the prevention of cardiovascular disease to a country-wide level. The results of the Italian Primary Prevention Project PPP [22] were extremely interesting, both because of the conclusions and because of the modalities of this trial. The PPP was a randomised controlled trial which tested the efficacy of low doses of acetylsalicylic acid (100 mg) and of vitamin E (300 mg) in the prevention of cardio-cerebrovascular events in patients with an intermediate risk profile. The analysis of the results of the study showed that acetylsalicylic acid had significant effect in reducing major cardio-cerebrovascular events and cardiovascular mortality. In particular, a 44% reduction in cardiovascular deaths was observed in the group treated with acetylsalicylic acid. The study also underlined the safety profile of the product.

The conclusions of the Italian Cardiolab project highlighted the fact that in the fight against cardio-cerebrovascular disease, significant results could be obtained through the dissemination of primary prevention. Moreover, the evidence derived from large randomised clinical trials indicates that acetylsalicylic acid is one of the possible tools in the fight against the risk of developing cardio-cerebrovascular disease.

Also, recent research from the World Health Organization confirms the importance of raised blood cholesterol as a risk factor for developing CHD. The World Health Report 2002 [23] estimates that around 8% of the entire disease burden in developed countries is caused by raised blood cholesterol levels, and that over 50% of CHD in developed countries is due to blood cholesterol levels in excess of the theoretical minimum.

If people with raised cholesterol and a predicted annual risk factor of greater than 1.5% were aware of that fact, it is likely that a proportion would choose to adopt strategies to reduce their risk. For some, effective cholesterol-lowering medications may be necessary and this could be an option for self-treatment.

In this context, statins are the treatment of choice. In combination with changes in lifestyle they have been found to reduce total cholesterol levels by 20-30% and low density lipoprotein cholesterol levels by 30-40%. The role of statins in primary prevention has been well established by studies such as WOSCOPS [24], where significant reductions in death from all causes were reported over the course of the five-year follow-up in non-CHD trial population.

Nowadays there is consensus that statins should be made available to all those at a moderate risk of developing CHD at 10 years. This is consistent with the latest evidence on cost effectiveness besides its impact in preventing hospital admissions for CHD. Nevertheless, the cost of identifying people at moderate risk as well as the cost of treatment makes it virtually impossible to treat them under the different public healthcare systems.

21. Cardio-cerebrovascular prevention; measures in the field. Clinical evidence, economic aspects, communication dynamics. Italy. May 2002.
22. Gruppo Collaborativo del Primary Prevention Project (2001). Aspirina a basso dossagio et vitamina E in soggetti esposti a rischio cardiovascolare; uno studio randomizzato in medicina generale. The Lancet (9250), 89-95
23. World Health Organization (2002). The world Health Report 2002. Reducing Risks, Promoting Healthy Life. World Health Organization: Geneva. Chapter 4
24. The West of Scotland Coronary Prevention Study Group. Prevention of coronary hearth disease with pravastatin in men with hypercholesterolemia. N Engl J Med 1995;333: 1301-7

CASE STUDY III

HEART DISEASE PREVENTION

COLLABORATIVE CARE THROUGH THE PHARMACY

CHD prevention could be treated in the framework of collaborative care through the pharmacy. Primary prevention of CHD through self-care requires the intervention of a healthcare professional to assess risk, give advice and monitor progress. In this context, pharmacists could play a key role in improving prevention and treatment.

Pharmacy's contribution to public health in several key areas has proven its efficacy in such a role. Screening, monitoring and treatment could be shifted to the pharmacy to allow people with a lower absolute risk of 15-30% to be treated. Obviously, in order to offer a complete service, pharmacies may specialise to be able to check patient profiles so that those with a higher risk of developing a CHD or with an occult disease (e.g. diabetes) can be referred to a physician. Moreover, the integration of the pharmacy into the CHD prevention model would provide substantial benefits to public health and have little impact on healthcare budgets.

CONCLUSION

Coronary heart disease is the single most common cause of death in the majority of European countries. CHD prevention is one of the main challenges facing European healthcare systems, as this type of diseases is for a large part responsible for the increasing costs of healthcare.

The growing trend of people taking a more active role in their own health care and their increasing awareness of and knowledge about CHD suggest that there is a widespread interest among the general population in preventing and reducing coronary heart disease.

The benefits of using statins in people with moderate risk are well documented. The thresholds for treatment are driven by economic questions leaving "low-risk" people without treatment when they could themselves take action to prevent a higher risk level or a coronary event.

CHD prevention should be treated in the framework of the collaborative care model involving the pharmacy as, unlike other non-prescription medicines, statins present self-diagnosis and monitoring challenges to patients.

Self-medication to prevent CHD, managed through the pharmacy, has the potential of providing major benefits to public health and reducing healthcare costs.

SUMMARY

The three case studies demonstrate the value of innovative non-prescription medicines for indications beyond those related to minor illnesses. Their availability without a medical prescription has the potential of increasing the likelihood of treatment and, by that, of reducing the number of sufferers. This option should never question the right and possibility to consult a medical doctor whenever a patient thinks this is appropriate.

In this context, it should also be recognised that the individual perception of the need for a medical consultation and diagnosis may differ. In addition, people's financial means for practicing self-medication are not the same. This situation, sometimes referred to as inequality in health, indicates that the availability of a medicine without a medical prescription should be seen in the context of enlarged choices for the individual without preventing any sufferer from seeking medical advice whenever needed.

In line with this reflection, the availability of a medicine without a prescription should be seen as completely separate from any considerations around the reimbursement of medicines. While the status of a medicine without prescription is related to its good safety profile, considerations around reimbursement are part of a social policy which is much influenced by the priorities and financial strength of the national healthcare systems. Any move of a medicine from prescription to non-prescription status should therefore not automatically put the reimbursement of such a product by the national healthcare system into question.

PART III:
POLICY RECOMMENDATIONS

70

Part III: Policy recommendations

As the public health and economic benefits of responsible self-medication have been widely demonstrated, many political institutions on a national and international level have started to consider concrete policy recommendations in order to realise the beneficial potential of responsible self-medication. While the value of self-care in general terms is widely recognised, a systematic debate on the skills needed to practise self-medication responsibly has not really taken place. This is in sharp contrast with the growing willingness of people to take more responsibility in moving from a passive patient to an active "self-care manager". Furthermore, changes and developments in society such as the rise in consumerism, a desire for choice and ease of access to healthcare services have created a fertile environment for self-care. Now seems to be the right moment to instil in people the confidence to act independently and to adopt a self-care behaviour that is an integral part of the way they look after their own and their family's health.

EDUCATION AND INFORMATION

In more concrete terms, this means that the wide range of information and education possibilities in existence should incorporate elements of responsible self-care. The key element of all these measures should be to indicate that self-care has proven its ability to enlarge the choices individuals have whenever they are faced with health problems. Due to differences in knowledge but also financial means, people should not feel forced to practise self-medication but regard it as a valuable option which in many cases provides the most efficient way of treating their health problems. This approach goes hand in hand with the wide recognition that an overall improvement in public health is not possible without increasing the responsibility of individuals for their own health. Providing options for self-treatment includes the potential of practising a self-responsible behaviour which may increase the overall individual understanding of issues affecting a person's health.

ROLE OF HEALTH PROFESSIONALS...

A key point in all future strategies is the availability of comprehensive and well-understandable information on self-care options, and in particular on the medicines available without a medical prescription. New challenges arise from the expansion of the range of medicines regarded as potentially appropriate for self-medication. The challenge for all partners in healthcare, including in particular medical doctors, pharmacists, nurses, patient organisations, regulators and medicine manufacturers, is to provide citizens with the necessary support to use the available resources in the best possible way. Healthcare professions will continue to play a crucial role in this overall concept. Therefore the university and post-graduate training of health professionals should regard education in the area of non-prescription medicines as a priority, including appropriate communication on treatment options. This should not only allow the best possible communication with sufferers about medicines, but particularly also address common questions likely to be raised by users and alternative treatment options that do not entail the use of a medicine. All this would have to be provided in an accurate and consistent form.

Part III: Policy Recommendations

...including in particular the pharmacist

Many of the daily counselling in Europe in the context of self-medication is carried out in community pharmacies. Beside a proper preparation of pharmacists and pharmacy staff with regard to self-care issues, it is particularly important to create an atmosphere in the pharmacy environment which encourages customers to raise their health problems and address questions to the pharmacy staff. A great deal of progress has been made in many pharmacies with regard to pharmacy design to allow this to happen. However, improvements can still be made and these might include a better presentation and visibility of non-prescription medicines in the pharmacy with the objective of stimulating debate on available treatment options. [1]

Equity in healthcare

In this context, it is important to stress that enlarging the range of medicines available without a prescription should not be related to possible measures to reduce their reimbursement. It is the objective of the debate around new indications for self-medication to increase personal responsibility for health and disease-related issues, with as a final outcome the provision of healthcare services in the most efficient manner. In many cases this includes a debate on possible dereimbursement measures. However the two debates should be kept separate. Experience has shown that dereimbursement only achieves the projected aims once a whole category of medicines – i.e. all medicines available for a certain indication – is taken out of reimbursement. Otherwise it is more likely that costs for social security systems will increase due to the high probability of medicines that are no longer reimbursed being substituted by medicines that are still reimbursed. This means that any link between a medicine's status as prescription or non-prescription and its reimbursement status should be avoided. The relationship between the move of a medicine from prescription to non-prescription status and the reimbursement of this medicine is particularly counter-productive as reimbursement is an important incentive to initiate a move to non-prescription status and de-reimbursement is reducing the options and consequently the potential benefit of responsible self-medication.

Proper regulation

There is a range of important regulatory parameters to allow the most appropriate development of the self-care environment in Europe. The relevant issues were particularly well addressed during the so-called G10 Medicines process and were clearly reflected in the G10 Recommendations [2] as well as in the Commission's Communication on these recommendations [3]. The major elements of these recommendations may be summarised as follows:

- In order to communicate the availability of non-prescription medicines, it should be generally recognised that all medicines classified as available without a

1. See also: Improving Visibility of Self-Medication in Pharmacies, AESGP, May 1998.
2. G10 Medicines Report, 7 May 2002: http://pharmacos.eudra.org/F3/g10/docs/G10-Medicines.pdf
3. A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, 1 July 2003: http://pharmacos.eudra.org/F3/g10/docs/G10_CommComm_EN.pdf

prescription should in principle have the right to be advertised to the general public in all media. This ensures the best possible communication with the objective of making sufferers aware of treatment options.

- In the context of the best possible communication, it is also important to recognise the value of allowing the same tradename for products moved from prescription to non-prescription status. Forcing manufacturers to change the tradename once a product is moved to non-prescription status makes communication with potential sufferers far more difficult as they would have to get acquainted with the new tradename. Moreover, it is important to recognise the value of the same tradename for different forms of non-prescription medicines and / or other self-care products as an efficient way of communicating the value of a product. Society is used to the general use of umbrella tradenames which are widespread in all kind of sectors, and it should also be possible to benefit from the related advantages in the pharmaceutical environment.

- All medicines – including all non-prescription medicines – need an authorisation before they can be put on the market. This means that they have to respect the legal requirements concerning quality, safety and efficacy. It is however necessary to make an adequate distinction between medicines with a completely new chemical entity and the wide range of non-prescription medicines which includes many well-known substances that, as a result, do not need to provide the same kind of data with regard to their safe and effective use. This has been recognised in the European Union's legal provisions by the establishment of the concept of well-established use and has been further specified for herbal medicines with a traditional use. A pragmatic use of the resources available to deal with non-prescription medicines within the regulatory authorities and the industry is therefore important.

Part III: Policy recommendations

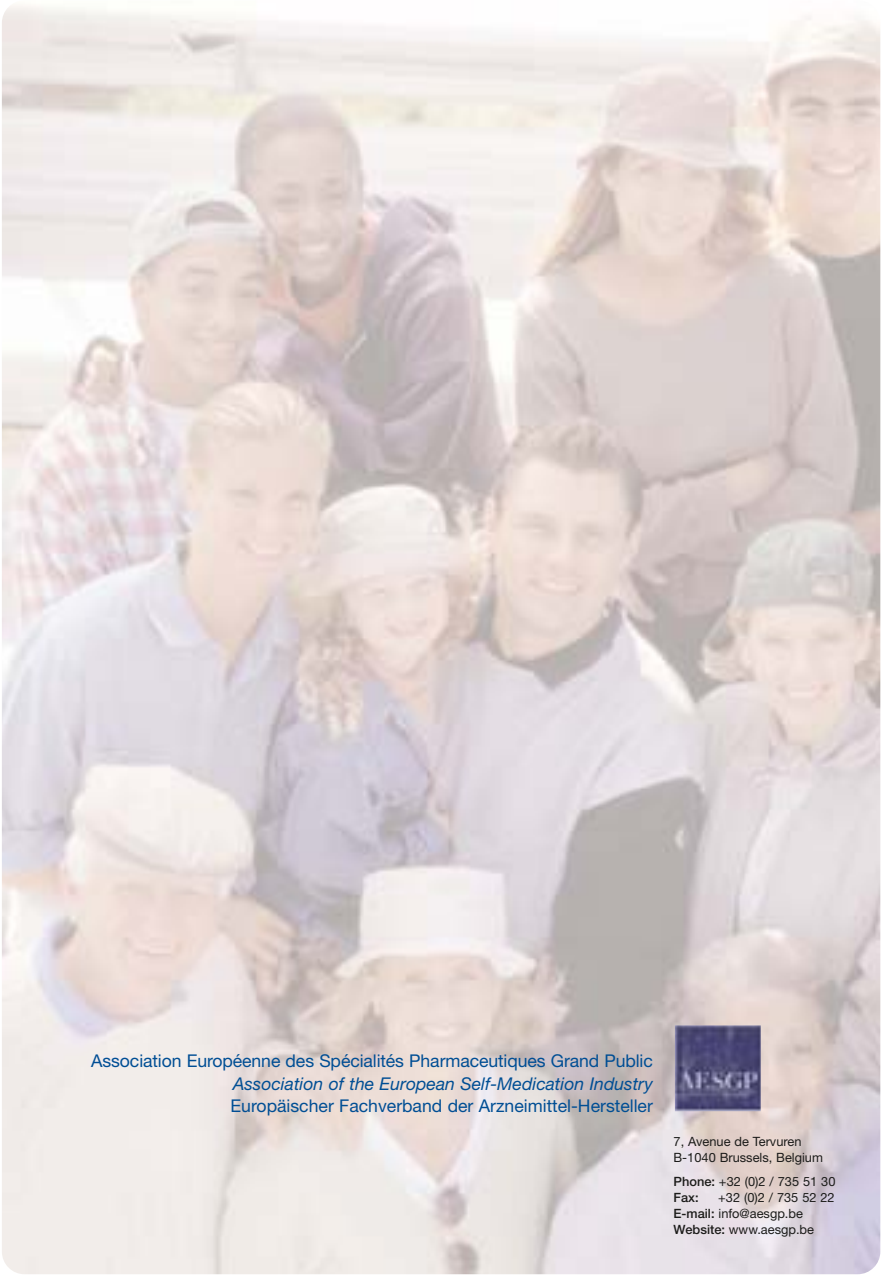
- Mechanisms to change the status of a medicine from prescription to non-prescription may need to be amended in order to allow for a sufficiently speedy and transparent process but also to create the right kind of incentives for manufacturers to move products to non-prescription status. New legal provisions with regard to data exclusivity decided at the end of 2003 need to be properly implemented on the national level in order to encourage manufacturers to file new applications.

- To ensure the safe and effective use of medicines, citizens need accurate information on the labels and in the leaflets in language they can understand. The information should be comprehensive and the content and design must reflect research carried out with consumers on accessing the information. The key is that they should be able to understand and act upon that information, and this must be the ultimate goal for regulators and manufacturers.

- Practical experience has shown that a free pricing system for manufacturers of non-prescription medicines allows the development of an appropriate price level corresponding to the market conditions in other areas. Free pricing also allows the financing of the work needed to bring the product to market and of appropriate communication with citizens. Any measures in relation to price control or price notification are therefore unnecessary for non-prescription medicines, and should be abolished.

- Governments should encourage citizens to practise responsible self-medication, for instance by allowing them to add the costs incurred for medication that is not prescribed by a medical doctor to their tax-deductible expenses.

Policy recommendations on an international level inevitably have to stay somewhat general as their concrete implementation in many areas depends on national culture as well as on the political and legislative environment. Therefore, any self-care care policy should – at least to a certain extent – be developed as part of a national healthcare policy, and specific needs should be addressed by a process on the national level. It is however hoped that this document, with the data collected and the recommendations made, becomes a helpful point of reference for such discussions, which should in the end be particularly beneficial for the citizens of Europe.



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