

Self-Medication in Europe: Economic and Social Impact on Individuals and Society

Selbstmedikation in Europa: Sozioökonomische Effekte auf den Einzelnen und die Gesellschaft

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ABSTRACT

Objectives To demonstrate the different monetary and time-related costs associated with the treatment of minor ailments (MAs) in the case of a general practitioner (GP) visit or self-medication with non-prescription medicines as an essential part of self-care in European countries. Ultimately, this is also intended to enable health policy statements with regard to an efficient allocation of resources in outpatient care.

Methods A simplified decision-analytical model is applied in which the self-purchase of a non-prescription medicine and a GP visit are considered as partial substitutes from the patient's perspective. In order to compare the decision paths of GP visit and self-medication in the sense of a cost-minimisation approach, the most relevant direct and indirect cost types are identified. Thirty countries are clustered following socio-economic criteria. The value of self-medication is calculated for an individual MA case per Country Cluster, then the data is extrapolated to the entire population of countries and aggregated to a European value. Status quo and potential scenarios as well as relevant perspectives (patient, GP, healthcare system, national economy) are considered. Sensitivity analyses are conducted.

Results Almost 1.2 billion MA cases are treated by self-medication in Europe p.a., saving EUR 26.31 billion in direct costs and EUR 10.41 billion in indirect costs (status quo). On average, one euro spent on OTC medicines by consumers saves national healthcare systems and economies EUR 6.70. 10–25 % of current GP visits could be substituted by self-care, creating an additional savings potential of EUR 17.60 billion.

Conclusion The study results reveal that self-medication in European countries is already associated with a high economic and social value for the individual and society. It is evident that current savings could be further increased by promoting self-care. Through responsible self-medication supported by an adequate health policy, resources and significant efficiency reserves for healthcare systems as well as national economies can be released. The resources freed up through an adequate self-care policy can play a significant role in building more resilient healthcare systems across Europe.

ZUSAMMENFASSUNG

Zielsetzungen Bei der Behandlung leichterer Gesundheitsstörungen führt die Inanspruchnahme eines Hausarztbesuchs zu anderen monetären und zeitlichen Kosten als die Selbstmedikation mit rezeptfreien Arzneimitteln. Die unterschiedlichen Kosten der beiden Behandlungsoptionen sollen auf europäischer Ebene aufgezeigt werden. Dies soll letztlich auch gesundheitspolitische Aussagen im Hinblick auf eine effiziente Ressourcenallokation in der ambulanten Versorgung ermöglichen.

Methodik Es wird ein vereinfachtes entscheidungsanalytisches Modell angewendet, in dem im Fall einer leichteren Gesundheitsstörung der Selbstkauf eines rezeptfreien Arzneimittels und der Besuch des Hausarztes als partielle Substitute aus Sicht des Patienten betrachtet werden. Um die Entscheidungspfade von Hausarztbesuch und Selbstmedikation im Sinne eines Kostenminimierungsansatzes zu vergleichen, werden die wichtigsten direkten und indirekten Kostenarten ermittelt. Dreißig europäische Länder werden nach sozioökonomischen Kriterien geclustert. Der Wert der Selbstmedikation wird zunächst einen einzelnen Behandlungsfall pro Ländercluster berechnet, dann werden die Daten auf die Gesamtpopulation der Länder extrapoliert und zu einem europäischen Wert aggregiert. Status quo und mögliche Szenarien sowie relevante Perspektiven (Patient, Hausarzt, Gesundheitssystem, Volkswirtschaft) werden dabei berücksichtigt sowie Sensitivitätsanalysen durchgeführt.

Ergebnisse In Europa werden jährlich fast 1,2 Milliarden Fälle leichterer Gesundheitsstörungen durch Selbstmedikation behandelt, wodurch 26,31 Milliarden Euro an direkten Kosten und 10,41 Milliarden Euro an indirekten Kosten eingespart werden (Status quo). Im Durchschnitt spart ein Euro, den die Verbraucher für rezeptfreie Arzneimittel ausgeben, den jeweiligen nationalen Gesundheitssystemen und Volkswirtschaften 6,70 EUR. Je nach Land könnten weitere 10–25 % der derzeitigen Hausarztbesuche durch Selbstbehandlung substituiert werden, was ein zusätzliches Einsparpotenzial von 17,60 Mrd. EUR bedeuten würde.

Schlussfolgerung Die Studienergebnisse zeigen, dass die Selbstbehandlung leichterer Gesundheitsstörungen mit rezeptfreien Arzneimitteln in Europa bereits heute mit einem hohen ökonomischen und sozialen Nutzen für den Einzelnen und die Gesellschaft verbunden ist. Die gegenwärtigen Einsparungen können durch gesundheitspolitische Maßnahmen zur Förderung einer verantwortungsvollen Selbstmedikation noch weiter gesteigert werden. Hierdurch können weitere Ressourcen und Effizienzreserven für die Gesundheitssysteme und die Volkswirtschaften freigesetzt werden.

Die so zusätzlich freiwerdenden Ressourcen können dazu beitragen, die Gesundheitssysteme in Europa resilienter gegenüber aktuellen und künftigen wirtschaftlichen Herausforderungen auszugestalten.

Introduction

European healthcare systems face increasingly scarce resources due to demographic development, medical progress and the COVID-19 pandemic [1]. This situation also affects general practitioner (GP) care in many European countries due to high patient demand and heavy workloads. Against this background, it is essential to enhance self-care initiatives to support the efficient and sustainable use of resources among European healthcare systems. This will ensure comprehensive and reliable access to healthcare and ease the burden on emergency departments and primary care. As over-the-counter (OTC) or non-prescription medicines (NPM) can typically be administered without prior medical consultation, this form of self-care, called self-medication, can save time and economic resources by reducing e. g. the use of prescription-only medicines and general practitioner (GP) visits [2–4]. Despite the potential individual and societal benefits that can be realised through self-care, it is today still insufficiently promoted and may be challenging to expand self-care activities [5].

Several authors have defined the terms of self-care and self-medication so far. According to the World Health Organization (WHO) “Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health worker [6].” Further, self-care as a broad concept encompasses hygiene, nutrition, lifestyle, environmental factors, socioeconomic factors and self-medication. As one element of self-care, self-medication

is the treatment of self-recognised minor ailments (MAs) by selecting and using approved medicinal products available without prescription [7]. This paper focuses exclusively on the health economic effects of self-medication according to this definition. Other measures practised in the context of self-care are not considered here. The reduction to self-medication offers significant advantages, especially with regard to quantification: The scope of the intervention can be clearly defined, since it refers exclusively to the use of officially authorised medicines. On the basis of the over-the-counter medicine packages sold, a reliable, robust data basis is thus available in the European countries. In general, non-existence of risks, either direct or indirect, when used correctly and/or if utilised without medical supervision, is among the criteria for the status of non-prescription medicine according to the legal framework in the EU [8]. These criteria limit the status of non-prescription treatment to self-diagnosable and self-monitored conditions. Only areas of application and groups of preparations that meet the basic requirements of self-diagnosis and substances that meet all the criteria for non-prescription status are discussed in the context of the present study. Whenever self-medication is mentioned in this text, the concept of self-medication as described before is always meant.

The current state of research reveals that self-care and self-medication are a widely accepted and practiced form of primary care across Europe [9–15]. Studies demonstrate that between 51 % and 94.9 % of Europeans are willing to practice self-care as it allows greater involvement in the treatment process, faster access to treat-

ment options for MAs and avoidance of long waiting times for GP visits [10, 16, 17]. A more evident shift in patient behavior towards self-care has been observed since the outbreak of COVID-19 and it is facilitated by self-care initiatives and frameworks to increase health literacy [18]. For healthcare systems and national economies, this means that an even greater potential exists to harness the value of self-care and there is an increased need to generate new quantitative evidence on the value of self-medication across Europe.

In recent years, self-care studies with a specific focus on quantifying self-medication have been conducted at the national level for Greece [19], Spain [20], Italy [21] and Germany [3] as well as one study focusing on seven European countries [22]. These studies consistently demonstrate that various positive effects can be achieved for national healthcare systems if a proportion of prescription-only medicines or unnecessary GP visits are replaced with responsible self-medication. A targeted literature search was conducted by Noone and Blanchette for 1990–2016, including data gathered from members of the World Self-Medication Industry and searches on PubMed, EBSCOHost, and Google Scholar. The authors identified 71 articles, of which 17 were included in the review. These revealed considerable value to patients, payers and employers as the use of non-prescription products for the treatment of common conditions or for symptom management (e. g. allergies, chronic pain, migraine, vaginitis, gastrointestinal symptoms, or common cold symptoms) resulted in cost savings and improved productivity [2]. However, there is no study that quantifies the overall value of self-care or more specifically self-medication on a European level. This identified research gap gave impetus for this research on the social and economic impact of responsible self-medication in Europe and leads to the following objective.

The starting point of the present study and its methodological approach is the finding, documented by market data, that people in all European countries buy non-prescription medicines frequently and to a greater or lesser extent [23]. These are usually used to counteract certain self-treatable health conditions. This type of self-medication is seen by consumers as a highly important course of action for corresponding complaints or symptoms. As market research, especially on the basis of consumer surveys, shows, a visit to the GP is often seen as the most obvious alternative to self-medication [4, 12, 24]. This is because the consultation of a GP also regularly leads to the use of a medicine in the case of corresponding treatment occasions. This can be a medicine that is therapeutically similar or even identical to the preparation available for self-medication. In the case of a GP prescription, medicines are reimbursed by the national health care systems according to their specific legal situation.

The objective of this socio-economic study is to demonstrate the different monetary and time-related costs associated with the treatment of MAs in the case of a GP visit or self-medication with non-prescription medicines. First, the cost savings in an individual case of using self-medication instead of visiting the GP (micro level) are used to quantify resource savings currently realised through self-medication on an aggregated level (macro level). Second, the cost savings in an individual case are used to estimate the additional effects that can be achieved in the future through an expansion

of self-medication. Ultimately, this is also intended to enable health policy statements with regard to an efficient allocation of resources in outpatient care.

The main focus is on the perspective of the consumer/patient and the public health system. Data will be generated across all European countries (EU plus UK, CH, NO). For reasons of simplification, this data will not be generated for individual countries, but for groups of countries and then aggregated for the whole of Europe.

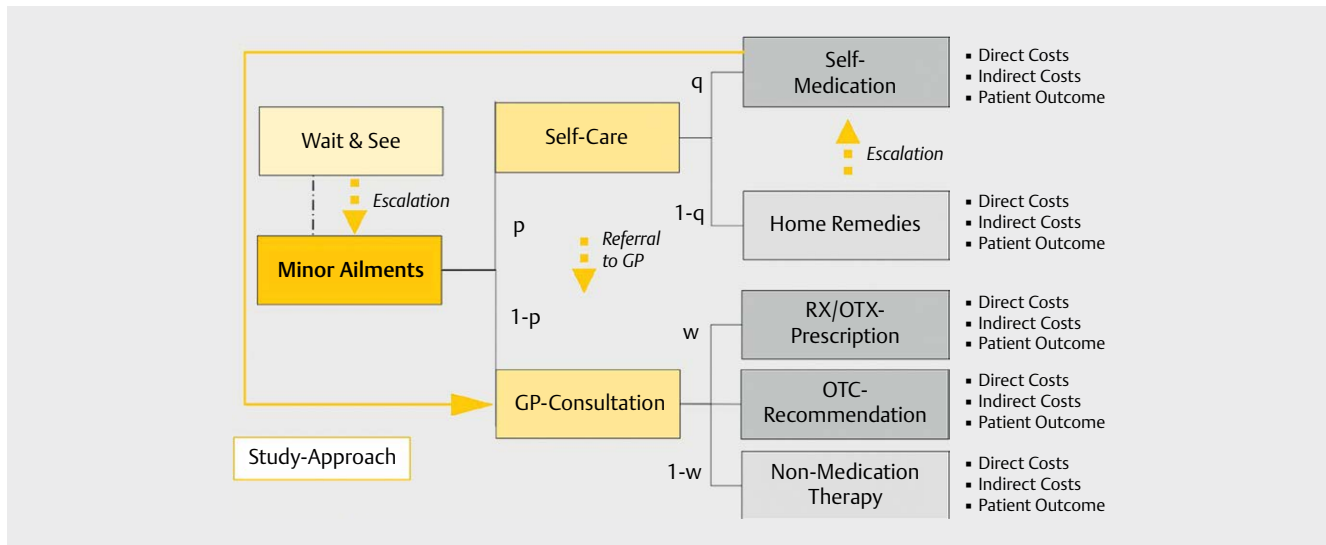
Methodological structure and steps of the model calculation

The study is based on an empirical analysis and representation of patient behaviour using a decision tree, which gives reason for the comparison of the treatment paths self-medication and GP resulting in a cost-minimisation analysis. Based on this, a multistep model calculation is carried out in order to calculate the corresponding economic costs on a micro- and macroeconomic level.

Decision tree model

Against the background of the outlined objective, a simplified decision tree model is applied. From the available market research studies and demoscopic surveys conducted in numerous European countries, broad insights into the behavioural patterns and decision-making situations of people confronted with a minor illness have been gained. The central findings of this data review form the basis for the decision tree presented below. That means, the decision tree shows the options which, on the basis of empirical and demoscopic data, have proven to be actually relevant courses of action for patients with minor health disorders. For the model calculation on the economic effects of self-medication, the frequency with which these decision paths are chosen in practice on an aggregated level is determined on the basis of market data and consumer surveys. Implicitly, each of the individual decisions of a patient or GP in this decision tree can be traced back to an expected utility model. However, for the purpose of this study it is sufficient to focus on the actual results of decision-making behaviour at the aggregate level.

In the event of a minor health problem, it is first of all up to the consumer to decide between "wait and see" to get better or becoming active in the form of a visit to the GP or self-care. On the second decision level, the consumer's alternatives in the case of self-care and the GP treatment options are presented. The latter has three basic options in the case of a consultation. First, the GP can prescribe a prescription-only (Rx) or a non-prescription medicine (OTX) which both can be reimbursed by national health care systems. The second option includes all forms of medicine recommendation that result in the patients having to pay for their medication out of pocket. The third option is for the GP to forego the use of medication, which is here referred to as "non-medication therapy" (see ► **Fig. 1**). Patients who consult a GP in the event of a minor health problem cannot predict in advance which of the three alternative courses of action the GP will choose. However, they can sometimes anticipate this based on past experiences and in some cases also influence it themselves. For their part, patients can make the decision to see a GP dependent on their expectations of what the GP will do. How the patients actually behave on an aggregated



► Fig. 1 Decision tree in case of a minor ailment.

level in this decision-making situation is known from consumer surveys and evaluations of GP contacts and OTC purchases (see “data needs and assumptions”) and can therefore be taken into account accordingly in this model.

The path with the greatest practical significance in the case of MAs is, according to the above-mentioned data, self-care. Within self-care the use of non-prescription medicines (self-medication) plays a significant role which is documented by the number of OTC-products sold throughout Europe [23]. Specifically, in relation to this option a consultation with a GP is often seen as an alternative from the patient’s point of view which in nine out of ten cases also results in the use of medicines and often also of OTC preparations. When consumers make a choice between the available treatment pathways, they often decide on the basis of their personal experience. A decision in favour of self-medication is typically based on the experience that symptomatic complaints in the course of MAs can be successfully treated with non-prescription medicines. Moreover, from the consumer’s point of view, the low-threshold access to this form of care is regularly relevant for the decision [3, 25]. To be precise, it is primarily the transaction costs associated with a GP consultation in the form of travel and waiting times that can support the decision in favour of self-treatment with non-prescription medicines.

Based on the assumption of a typical and ordinary course of treatment, the possibility of potential complications or treatment failure is not explicitly presented in the decision tree. Implicitly, however, it is not excluded to such a degree as a return to the starting point and thus a new decision-making process (possibly with a different outcome) may occur. Consequently, the decision in favor of a certain therapy was equated with the (successful) endpoint of the decision tree.

In principle, each path in the decision tree is associated with a certain benefit and costs, which can be evaluated and compared in a cost-benefit analysis.

Nevertheless, the entire study was limited to a cost-minimisation analysis. Accordingly, this study does not examine or consider whether the expected benefit of self-medication is equivalent to that of medical treatment for a minor health disorder. Meanwhile, this simplification appears to be permissible for several reasons. Firstly, because the consideration was limited to mild and regularly self-limiting health disorders. By definition, such health disorders as the common cold or minor stomach complaints disappear again after a few days even without treatment [4]. The medicinal products available without prescription in Europe (OTC preparations) are suitable, effective and safe according to their official authorisation for the self-responsible treatment of just such complaints [8]. Only areas of application and groups of preparations that meet the basic requirements of self-diagnosis and substances that meet all the criteria for non-prescription status are discussed in the context of the present study. In addition, consumers decide in favor of self-medication on the basis of their own benefit assessment. They regularly do this based on a broad knowledge of experience in dealing with minor health disorders, which is either gained individually or passed on in the family [26–29]. By deciding in favor of self-medication, it becomes obvious that the expected benefit in the specific case is considered at least equal to that of a visit to the GP.

With reference to the described relationship between the two therapy alternatives and the premises derived from it, calculations are carried out below on the cost differences between self-medication and GP visits at the individual and aggregate level.

In summary, it can be stated that the approach described initially implies that in certain cases of minor health disorders, visiting a GP and using OTC medicines self-responsible are equivalent alternatives for solving these health problems. However, the associated treatment costs are very different for the two treatment pathways. In every case in which an individual patient decides to self-medicate, the burden on the public health system is obviously reduced, since costs for a GP visit and for prescribed medication are avoided in particular. These costs, which are borne by the rele-

vant payers in the respective national healthcare system, are direct costs. In the case of self-medication, there are also direct costs in the form of the costs for the OTC preparations. These are now usually borne by the consumers themselves. The costs of both therapy paths also differ at the level of the national economies. In the case of a GP visit, there may be work absenteeism and loss of productivity if the GP visits take place during working hours or if the GPs issue sick notes. These costs are known as indirect costs and are usually borne by the economy or society as a whole.

The cost differences that arise in individual cases can be multiplied by the number of currently practiced self-medication cases in order to determine the aggregate cost difference between self-medication at national or European level. It is also possible to calculate what additional cost effects would occur if more people self-medicated with OTC medicines instead of seeing a GP.

Steps of the model calculation

In the following, the basic procedure of the analysis and the calculation steps of the model are outlined. The description of the model is followed by an explanation of where and on which basis data and assumptions were used in the model calculation.

The figure shows the three different result levels A, B and C of the model on the left-hand side. On the first level, the average costs of a single treatment case are determined for the paths of self-medication and a visit to the GP. In this way, the cost difference between the two treatment paths is determined. These calculations are carried out at the aggregated level of so-called Country Clusters. For reasons of simplification, these clusters combine countries that are relatively similar with regard to relevant factors (so-called key parameters), thus the costs of the treatment pathways can be determined uniformly for the respective countries (see explanation in section *Data needs and assumptions*). This ultimately means that for countries combined in one Country Cluster, the cost differences between a GP visit and a self-medication case are assumed to be equal.

The results of the first level are thus cost differences per case between the treatment paths GP vs. self-medication, each related to the Country Clusters formed. These results of level A (A4) are used as a starting point for further calculations on the second level (B) and also on the third level (C). On the second level B, the savings currently achieved in the individual clusters through self-medication are calculated by multiplying the cost difference per case with the corresponding number of relevant cases in the cluster. The multiplier used for this is the number of self-treatment cases that currently take place instead of a GP visit. The starting point for this calculation is the number of OTC packs purchased directly by consumers as a substitute for an otherwise required GP visit. In other words, if these OTC preparations would not have been available without a prescription, a GP visit would have taken place. By adding up these saving effects per cluster, the results of the level B are the total savings that are currently achieved through the practised self-treatment cases in Europe. In the presentation of the results, this level B is referred to as the Status Quo Scenario.

The third level of the model calculation (C) aims to determine which further saving effects would be achievable through self-medication in the future if an additional share of the GP visits due to MAs that take place today were replaced by self-medication. For

this purpose, it is calculated which direct and indirect costs would be avoided if a certain proportion of patients who consult a GP today in cases of a self-treatable ailments were to treat themselves with non-prescription medicines in the future. Determinants considered for direct costs were treatment costs at the GP office and drug costs for Rx and/or OTC drugs per case. For the calculation of indirect costs, costs of lost working time due to travel, waiting and treatment times at the GP office and / or pharmacy as well as days of absence from work due to sick leave were calculated. In addition, patient time invested in traveling, waiting and if necessary treatment are shown as intangible costs. This calculation also takes the savings per self-medication case from level A as a starting point. The multiplier in this scenario is the number of additional GP cases per Country Cluster that could be avoided through self-medication. These result from the expansion potential of self-care in each country as explained in section *Data needs and assumptions*. By adding up the corresponding values per cluster, the additional achievable saving potentials for Europe are calculated if more people self-medicate for minor health disorders in the future. In the presentation of the results, this level C is referred to as the Future Scenario.

The outlined analysis and calculation steps thus begin at the microlevel with the individual decision situation of a single person faced with the choice of a treatment path for his or her minor health disorder (decision tree). The transition from the microlevel to the macrolevel takes place on the second and third result level (B and C) respectively at the transition from B2 to B3 and from C2 to C3. That is, where aggregated savings effects are calculated at the cluster level (and then at the European level) by multiplying costs per case by a case number representing the expansion potential of self-care.

Data needs and assumptions

In the course of the outlined calculation steps, a large number of data and some assumptions are required. The nature and origin of these data and the rationale behind the assumptions used are summarised as follows. In the entire first level of the model calculation (A), the basic data is derived from research in statistical databases and publications. In particular, data were sought that provide information on the direct and indirect costs of a case of treatment in the individual European countries. Accordingly, data on all costs associated with self-medication, i. e. in particular OTC prices and time costs, for example for visits to the pharmacy, were determined for all countries considered. Likewise, the costs for GP's orders, prescribed medicines and economic costs, especially for absences from work, were determined at the level of individual countries or, if applicable, country groups. The corresponding cost weights used in the calculations can be found in the tables in the appendix. On this data basis, the cost difference between a case of treatment at the GP versus in self-medication was determined. These statistics-based calculation results are also the starting point for the calculations on the second (B) and third result level (C).

The search for suitable data was conducted primarily via the search engines Google and Google Scholar and specifically on statistical databases as Eurostat and OECD database. The search terms used corresponded to the data searched for in the respective case (see **supplementary material**). In order to have as homogeneous a database as possible, the most suitable data were selected by

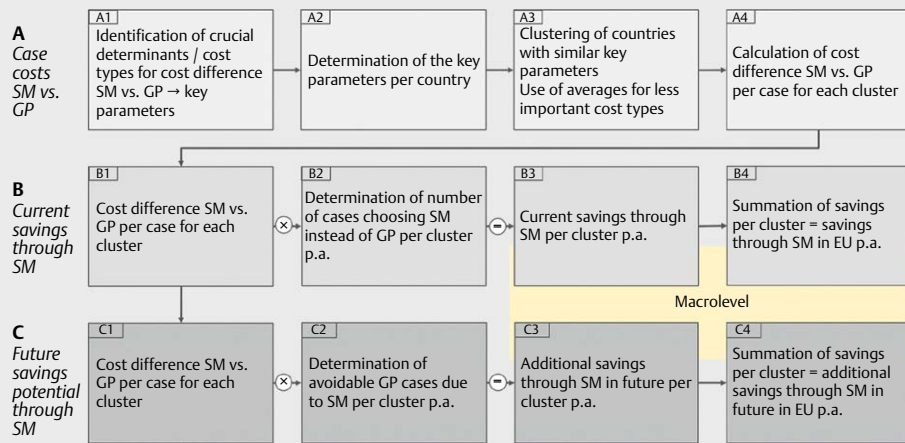
prioritizing those in which several countries were represented at once by authorities or organizations (e. g. Eurostat, OECD). In addition, efforts were made to use the most recent data available. These comparative data are usually provided in English. If no sources were available for the required data, in which several countries were represented at once, an individual search was carried out at the national level for each country. Here, in particular, data from official sources (e. g. authorities or organizations) were used for the data selection and again efforts were made to ensure that the data were as recent as possible. Moreover, exclusively for this project provided market data by IQVIA on sales volume and turnover of Rx and OTC preparations in 28 European countries were used as well as different surveys on the behaviour of consumers. Due to the translation option provided by Google Translate, it was not necessary to limit the search to a specific language.

The grouping of countries into Country Clusters, also carried out on the first level (A), was necessary for reasons of accessibility of data and manageability of data gaps from 30 European countries. The clustering is based on the fact that countries are grouped together that are relatively similar with regard to the characteristics of certain key parameters. These were identified to have a significant impact on the cost difference of self-medication and GP visits in a country. The criteria for the grouping were different cost types, namely GP costs (treatment costs per case), drug costs and labour costs respectively costs for absence from labour (measured on the basis of average costs per working hour) (see **supplementary material** for more details). On the basis of the literature reviewed and previous health economic studies on the economics of self-medication, these could be identified as the most influential costs with regard to the cost difference between the treatment paths of GP versus self-medication. The costs for non-prescription medicines and prescribed medicines in the respective areas of treatment are obtained from the statistics of the market research institute IQVIA. Relevant statistical publications from European and international databases are used to determine the costs for GP visits and lost working hours (see **supplementary material** for more details). Countries that are similar with regard to these three key parameters were categorised into a total of eleven groups. European average values for all countries and clusters were used for a number of other cost types that account for the difference between the GP and self-medication treatment pathways. These so-called basic parameters are costs that are quantitatively less significant and also relatively similar in all countries under consideration. This applies less to monetary factors, but rather to time costs such as travel costs (e. g. travel time to GP visit). Using these data, the direct and indirect effects of self-medication were calculated based on productivity losses due to absenteeism from work, the opportunity costs for GPs and patients, pharmaceutical expenditure, and medical expenditure. The following table shows exemplary for two Country Cluster the comparison of these effects in a single minor ailment case.

At the second and third level of the model calculation (B and C), values based on assumptions were used in each case for the box in the second column (B2 and C2). At level B, this concerns the number of self-medication cases that actually replace a GP visit. Basically, the Europe-wide data on the use of OTC products that are included in the calculations are based on the market statistics from IQVIA that were exclusively available for this project. These statistics contain figures on turnover and sales in all countries considered here. Additional insights

into the extent to which these OTC preparations were used instead of a possible visit to the GP could be drawn from demographic and empirical surveys on consumer behaviour. That means, to derive the number of self-medication cases, only a certain share of the current number of sold OTC packages documented by market statistics per country is used as a multiplier. It is e. g. taken into account that not all OTC preparations sold are used in treatment situations that would alternatively have caused a GP consultation (e. g. very minor complaints or prevention). In addition, a further part of the OTC packs is deducted due to the fact that for a subgroup of current OTC purchasers, the alternative is not to visit a GP but to do nothing. Moreover, it was taken into account that in one case of a MA, it is not necessarily given that only one pack is used or that it is completely used up. The surveys used mainly refer to the preferences and actual behaviour patterns of consumers in dealing with minor health disorders. From these market data and surveys it could be derived beforehand that self-medication and GP visits are considered as substitutes in certain MA cases by a significant part of the consumers. The relevant frequencies in the decision tree which the respective pathways are chosen with can be derived from these data and surveys.

At level C of the model calculation, certain assumptions had to be made in order to calculate which so far unexploited potential still exists in the individual countries to replace a part of the currently occurring GP visits with self-medication. Estimates and assumptions on these questions have to be derived on a country-specific basis, since the significance of self-responsibility in health in general and the actual use of self-medication in particular differ greatly within Europe. A central role with regard to the development potential of self-medication is played by the number of medicines available without prescription in the country. It is evident that certain health disorders can only be treated by self-medication if non-prescription preparations are available for the corresponding indication in a country. The latter is determined using a database on the OTC status of medicines in all European countries [30]. As the availability of OTC products is obviously a necessary condition for self-medication to be practised [21, 31, 32], this condition is not yet sufficient since the population must also be willing to use these preparations. Against this background, the estimation of the development potential is based firstly on how many over-the-counter medicines are available or how many more Rx-t-OTC switches are still possible and secondly on the extent to which the given potentials for self-treatment are currently already being used by the population. In a country where only a comparatively limited number of substances or preparations are available without prescription, there is thus still relatively high growth potential for the concept of self-medication. In addition, the country-specific situation with regard to the incentives that favour or inhibit a decision to self-medicate at the individual level in turn has an effect on the actual uptake or use of the available OTC medicines and the significance of self-medication as a therapy option. This assessment was made on the basis of the four criteria self-medication packs per capita p.a. [23], market share of self-medication in the pharmaceutical market [23], GP contacts per capita p.a. [33] and willingness to practice self-care among the population [34]. In short, the fewer substances are available without a prescription and the less the existing substances are already used for self-treatment today, the higher the potential for future growth in self-medication by substi-



► Fig. 2 Methodological steps and result levels of the model calculation.

► Table 1 Exemplary cost comparison for two Country Clusters in a single minor ailment case

Cost Comparison Physician vs. SC for a Single Case of Minor Ailment				
Country Cluster 5: Czech Republic, Hungary, Latvia, Poland, Portugal, Romania, Slovakia, Cyprus, Malta				
		Physician Treatment	Self-Care	Cost Difference
Direct Cost	Medication cost OTC (EUR)	1,28	2,70	1,42
	Medication cost Rx (EUR)	3,94		- 3,94
	Treatment cost physician (EUR)	9,29		- 9,29
	Time cost physician (min)	11,16		- 11,16
Indirect Cost	Treatment-related work loss (EUR)	1,92		- 1,92
	Treatment-related work loss (min)	9,68		- 9,68
	Absence from work due to sick leave (EUR)	2,38		- 2,38
	Absence from work due to sick leave (min)	12,00		- 12,00
Intangible Cost	Time cost patient (min)	114,76	8,68	- 106,07
Country Cluster 8: Norway, Switzerland, Denmark				
		Physician Treatment	Self-Care	Cost Difference
Direct Cost	Medication cost OTC (EUR)	3,14	6,61	3,47
	Medication cost Rx (EUR)	13,95		- 13,95
	Treatment cost physician (EUR)	27,69		- 27,69
	Time cost physician (min)	11,16		- 11,16
Indirect Cost	Treatment-related work loss (EUR)	6,94		- 6,94
	Treatment-related work loss (min)	9,68		- 9,68
	Absence from work due to sick leave (EUR)	8,60		- 8,60
	Absence from work due to sick leave (min)	12,00		- 12,00
Intangible Cost	Time cost patient (min)	114,76	8,68	- 106,07

tuting GP visits in the respective country. By estimating the corresponding country figures, the potentials of the Country Clusters and, in the next step, the development potentials of self-medication in Europe as a whole were extrapolated.

By combining the two determinants availability and degree of utilisation of self-medication, countries in which the parameters are both low, both high or mixed are grouped. For these groups of European countries different growth potentials for self-medication are determined (see ► Fig. 2). This growth potential is based on a potential expansion of self-medication as an alternative to consulting a GP. The assumptions used for this forecast are quantitatively based on market developments documented after Rx-to-OTC switches and after changes in the incentive situation for consumer decisions to self-medicate (e. g. through legislative measures) in different countries [3, 9–12, 19–21, 35].

The model inputs included data from e. g. EuroStat, Organisation for Economic Co-operation and Development Statistics (OECD. Stat) and World Bank as well as real-world datasets from IQVIA. These were supplemented with evidence from the literature review. Additionally, a database consisting of country-specific data and estimates was developed for each of the 30 countries. Finally, sensitivity analyses were carried out.

Results

For all eleven Country Clusters identified, the total direct costs for choosing a general practitioner (GP) visit are significantly higher than those for choosing self-medication to treat an minor ailment (MA). Moreover, indirect costs (time costs of GPs, treatment-related work loss, sick leave-related work absenteeism) and intangible costs are of interest when examining saving potentials achievable through responsible self-medication. Aggregating these Country Cluster values leads to the total economic effects at the European level shown in ► Tables 2 and ► 3.

The tables demonstrate the cost difference between the GP treatment and the self-medication pathways. When interpreting these cost differences, positive figures indicate higher costs for self-medication while negative figures reflect savings achievable through self-medication. The substitution volume reflects the number of MAs treated by self-medication which substitute GP visits and thus leads to current savings. It is based on the number of packs of non-prescription medications sold and the share of patients which would have visited a GP if self-medication was not available.

In the status quo, around 1.2 billion cases of MAs are treated by self-medication in Europe per year, generating savings for health-care systems and society [35, 36]. The calculations show considerable savings for all types of costs and from almost all considered perspectives. Only the patients' pharmaceutical expenditure is higher in the case of self-medication, but this is offset by the significantly higher savings from GP visits. In addition, there are substantial individual time savings. In case of worsening symptoms or the occurrence of undesirable side effects, patients are advised to consult a GP. Due to the fact that the approval and the decision for the OTC status ensure in principle that the substances and application areas are suitable for self-medication and can be treated without a GP, it is assumed that this case rarely occurs. For this reason, no re-

liable data on this is available and this aspect was thus not integrated into the calculations.

Focusing on time saved by GPs due to the treatment of MAs with self-medication, about 120,000 more GPs would be required in the status quo. Alternatively, each GP working in Europe would have to work 2.4 hours longer per day, if self-medication was not available.

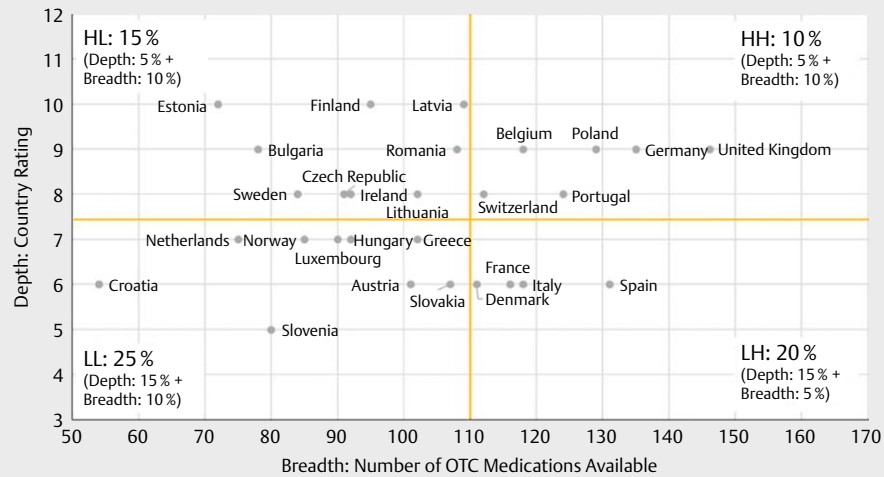
In addition to this existing relief for GPs, patients who practice responsible self-medication instead of visiting a GP save an average of 106 minutes in travel, waiting and treatment time. About

► Table 2 Cost savings in the status quo – Europe total

Cost Savings in the Status Quo Scenario		
	Substitution volume of MAs per year	1.19 bn
Direct Cost	Total medication cost (EUR)	– 6.21 bn
	Treatment cost GP (EUR)	– 20.10 bn
Indirect Cost	Time cost GP (hours)	– 221.25 m
	Treatment-related work loss (EUR)	– 4.65 bn
	Treatment-related work loss (hours)	– 191.92 m
	Absence from work due to sick leave (EUR)	– 5.76 bn
	Absence from work due to sick leave (hours)	– 237.83 m
Intangible Cost	Time cost patient (hours)	– 2.10 bn

► Table 3 Cost savings from different stakeholder perspectives – Europe total

Cost Savings from Different Perspectives		
	Substitution volume of MAs per year	1.19 bn
Patient Perspective	Total medication cost (EUR)	850.21 m
	Patient contribution per GP visit (EUR)	– 3.44 bn
	Time cost patient (hours)	– 2.10 bn
GP Perspective	Time cost GP (hours)	– 221.25 m
National Healthcare System/ Health Insurance Perspective	Treatment cost GP (EUR)	– 16.65 bn
	Medication cost Rx (EUR)	– 6.54 bn
	Total cost savings (EUR)	– 23.18 bn
National Economy Perspective	Absence from work due to sick leave (EUR)	– 5.76 bn
	Treatment-related work loss (EUR)	– 4.65 bn
	Total cost savings (EUR)	– 10.42 bn
	Absence from work due to sick leave (hours)	– 237.83 m
	Treatment-related work loss (hours)	– 191.92 m



► Fig. 3 Potential scenario: Substitution from general practitioner visits to self-care.

22 minutes (21%) of this time can be attributed to working time. This corresponds to an economic value of EUR 9.30. From the perspective of national economies, on average twelve minutes of sick leave can be avoided per self-medication case. This corresponds to an economic value of EUR 4.84 that can be obtained per self-medication case. Thus, each self-medication case saves, on average, EUR 14.14 in total for the national economy.

The sensitivity analyses carried out verified the robustness of the calculation results from the economic model.

The potential for expanding self-care beyond this existing scope can be identified in two directions: 1) facilitating access to more people in already established areas of self-medication (“depth”) or 2) increasing access by adding new active ingredients and/or indication areas where responsible self-medication has not yet been practiced (“breadth”) taking into account the specifications of the European Commission’s Switch Guideline [37]. Based on these considerations, different development potentials for national constellations represented by four quadrants (► Fig. 3) were determined.

The unexploited self-medication potential is approximately 10% to 25% of current GP visits in the respective countries. Against this background, country-specific potentials were calculated and weighted on a per capita basis to form a pan-European potential scenario.

The savings in direct and indirect costs already realized in the status quo result in a total of EUR 36.72 billion (see ► Table 2). Additionally, further potential savings of EUR 12.53 billion direct costs (total medication costs & treatment costs physician) and EUR 5.07 billion indirect costs (treatment-related work loss & absence from work due to sick leave) which adds up to EUR 17.6 billion can be realistically achieved through an uptake of responsible self-medication. That would amount to a further 48%. Thus, self-medication can save a total of EUR 54.32 billion in direct (EUR 38.84 billion) and indirect (EUR 15.48 billion) costs if the potentials that are already possible were exploited. The percentage savings potential may be extrapolated to all sub-groups of costs and the savings from

different perspectives. If it is assumed that the change in legal framework conditions that would be necessary to exploit the potentials of self-medication in this way would take a period of several years, the savings potentials mentioned here would have to be discounted accordingly to their present value. In accordance with health economic guidelines, the authors propose a discount rate of 3% p.a. as well as sensitivity calculations with 0% and 5%.

Again, the impact on GP time is of particular interest due to its importance for the supply of healthcare in national healthcare systems as an uptake of self-medication has the potential to free up GP resources [38]. Derived from the results presented in ► Table 2 above, there is the potential for 58,000 GPs to be freed up by the increased uptake of self-medication or that all GPs in Europe could work about one hour less per day. Alternatively, this hour could be redirected to treat more complex health conditions.

Discussion

Self-care is gaining additional interest due to increasing financial pressure on healthcare systems and the need to find a strategy to support primary healthcare. Since only self-medication is quantifiable, this study aims to measure the associated effects in order to contribute to the understanding of the overall value of self-care. This socioeconomic study adopts existing methodological approaches for the quantification of self-medication and develops them further to evaluate European countries in terms of access to and uptake of responsible self-medication from different perspectives. The single treatment case comparison of the direct costs in the two investigated treatment pathways, GP and self-medication, demonstrates significant cost differences between the treatment pathways and between the Country Clusters. This is caused by the different socioeconomic structures of the European countries. Despite differences in savings, it is evident that self-medication is already a source of substantial economic and social benefits in Europe.

The cumulative calculations for Europe demonstrate direct cost savings and a significant reduction in indirect costs through self-medication. The latter includes expenditures due to time gained from saved GP visits and the lowered sick leave-associated losses of work productivity. These yearly costs would otherwise be incurred by the national healthcare systems and by national economies. Moreover, healthcare professionals and individuals gain substantial benefits in terms of time spent. Freed up GP time may be allocated to more urgent or complex medical cases. Higher medicine costs solely arise from the patients' perspective which should be outweighed by monetary savings from avoided GP visits (co-payments) and considerable time savings.

Additionally, future potential savings vary in their extent depending on the country and also have an impact on the strained situation in medical practices in many countries. The unexploited self-medication potential is equivalent to the proportion of GP visits that could be substituted by self-medication. This effect has been discussed in various European studies and is often expressed in terms of time spent and appointments allocated to MA cases during GP visits or as the number of avoided GP visits resulting from a switch from prescription-only to OTC medicines [21, 39, 40]. The identified potential of freed GP resources can especially benefit severe cases of illness and reduce waiting times for patients [41, 42]. Thus, access to healthcare services can be enhanced in many countries across Europe through increased responsible self-medication.

Overall, this study demonstrates that self-medication delivers both social and economic benefits to individuals, healthcare providers, healthcare systems, national economies and society. Moreover, it emphasizes the advantages of self-medication: From the patient perspective this is a time saving low-threshold access to medicines appropriate to treat their MAs, GPs save time as well, there is less time lost in productivity and the healthcare systems save expenses on medicines and GP visits. There is also great potential for individuals to gain increased benefits by engaging in more self-care practices. However, self-care is still not perceived as an essential pillar of healthcare systems. There is a lack of targeted policy measures that provide incentives at the individual and collective level to promote self-care. With adequate self-care policy, issues that may result in reluctance to practice self-care at the individual level, such as limited understanding on the normal progress of symptoms, including severity and duration, or lack of knowledge on medicines that may be available without prescription, can be avoided [43, 44]. In line with the WHO guideline on self-care interventions for health and well-being, coherent healthcare policy and regulation supporting self-care are required to increase self-care uptake and ensure that self-care interventions take place in a safe and appropriate enabling environment [45]. Additionally, greater health literacy initiatives as well as greater access to health information is necessary to ensure that individuals understand and are able to practice responsible self-medication as an important element of self-care based on credible health information.

In interpreting the findings of this study, the following limitations need to be considered. The study is based on a dataset on various parameters that highlight treatment-related expenses, healthcare system coverage and average labor costs in 30 European countries. The quality, including completeness and how recent the data

is, depends on data availability. This differs across the 30 European countries and resulted in the need to utilize statistical methods to generate an average value for some datapoints. Nevertheless, the Country Cluster approach improves these estimates and enables the value of self-medication to be determined in countries previously lacking data. Although the present study does not focus solely on Rx-to-OTC switches and hence, the results are not fully comparable to previous European studies, it is evident that the future potential value of self-care is closely linked to the availability of non-prescription medicines in each country.

Furthermore, the development and implementation of the health economic model have highlighted that, as in any economic model, certain premises and assumptions must be made both for the calculations of the status quo and, to a greater extent, for projections on future scenarios. Corresponding limitations are always stated when first appearing in this study and are in any case based on the current state of research and relevant literature.

The potential costs associated with the misuse of OTC and Rx medicines are not considered in this study. Based on evidence, it is assumed that self-care is practised by the patient under either the guidance of a healthcare professional or by following product information. For prescription-only medicines, it is assumed that GPs prescribe according to adequate guidelines and in the interest of the national healthcare systems as well as patients. The latter can be classified as a restrictive assumption that leads to rather conservative results. This is due to the fact that potential effects of over-, under- and misuse of prescription medicines are in consequence not considered.

The risks that may be associated with an expansion of self-care are, by their very nature, the same as those that apply to existing self-care. It is obvious, however, that these risks could increase if the scope of self-care was to go significantly beyond what is practised today. The limits of self-care are of course exceeded at the latest when self-diagnosis is not possible and/or e. g. a prescription for prescription-only medicines and/or close monitoring of the condition is required. In this case, seeking self-care could worsen the health or the healing chances of the patient and would not be justifiable as a responsible treatment choice.

Therefore, the criteria for the status of non-prescription medicine according to the legal framework in the EU limit the status of non-prescription treatment to self-diagnosable and self-monitored conditions. Also, in the case of reclassification, national medicines agencies or the EMA re-examine the risks and benefits of a medicine in the self-care context. Moreover, the respective pharmaceutical form, dosage and package size with regard to the suitability for self-care are also examined and they will often differ from prescription-only medicine in order to minimise risk. Last but not least, the question of whether the patient can correctly recognise the symptoms and whether the patient can self-administer the medicine plays a role. If there is a risk that an incorrect self-diagnosis and thus, an incorrect self-care action can lead to a worsening of the actual disease, this will often result in a negative opinion regarding a marketing authorisation application. If, in practice, a risk emerges which cannot be effectively addressed by risk mitigation measures, a re-switch, i. e. the reclassification from non-prescription to prescription-only status, will be carried out by a medicine regulator.

Only areas of application and groups of preparations that meet the basic requirements of self-diagnosis and substances that meet all the criteria for non-prescription status are discussed in the context of the present study. The fact that a prudent further development of self-care within these defined limits could be clinically questionable is not supported by scientifically applicable findings and can therefore be disregarded at this point. However, it must be noted that with increasing access to diagnostic tools, for example symptom checkers, in vitro diagnostic tests, etc. there is a possibility that the number of self-treatable indications will significantly increase in the future.

When discussing and weighing the clinical risks and limits of self-care, it should also be taken into account that the danger of misdiagnosis, non-recognition and thus delay of illnesses can not only go hand in hand with increased self-care, but is also intensified when health systems are overburdened and, for example, GPs are forced to diagnose and treat important cases under de facto already high time pressure. The fact that this situation is already a reality in many medical practices has been pointed out internationally in various studies ever since the controversy on this problem ("To err is human") was initiated in the USA about 20 years ago. Today the lack of time is one of the reasons most often cited in professional circles for the fact that there is a corresponding error rate, especially in diagnosing [46–51]. A particularly high lack of time occurs in the practices of GPs at peak times of the cold and flu season and thus in connection with consultation occasions where more self-care would be conceivable [51–53].

Methodological limitations relate to the Country Cluster approach used to analyse the 30 different European countries. Country Clusters were formed based on certain identified parameters. Taking into consideration the similarities that countries of the same Country Cluster share, cluster-specific averages were formed for some values included in the economic calculations. Such cluster-specific averages may lead to the finding that individual values slightly deviate from the values in single countries or in clusters containing only one country. Apart from cluster-specific averages, it was necessary to calculate some European averages due to a lack of data on indirect and intangible time costs. These time costs include patient travel time and waiting time, where existing data does not cover all 30 European countries under consideration.

Finally, a limitation can be attributed to the complex nature and considerable differences between national remuneration systems for GPs and patient contribution systems. The differences in national remuneration systems for GPs make it impossible to point out certain influences on GP income that relate to the treatment of fewer patients. This is the reason why the GP cost was considered as income per minute/hour of working time that is based on average income and working time. Additionally, when examining the cost impact from the patient perspective, patient contribution per Rx prescription under the national healthcare system coverage varies according to country and patient group (e. g. elderly, low-income and young children). Therefore, an estimation of the patient contribution per Rx prescription was made based on the average amounts identified in each of the 30 countries. This European average may therefore not reflect the total monetary benefits that

can be realised by specific groups of patients under special schemes in the healthcare system of their respective countries.

Conclusion

National healthcare systems all over Europe are facing a scarcity of resources including general practitioner (GP) shortages and financial challenges. Against this background, the economic and social value of self-medication in the status quo in Europe was examined. The common approach developed in this study to determine the economic and social value of self-medication in Europe has enabled the generation of new economic evidence for public healthcare systems. It provides an up-to-date database on the value of self-medication in Europe that enables cross-country analysis on self-medication access and uptake.

The study results reveal that self-medication in European countries is already associated with a high economic and social value for the individual and society. It is evident that current savings could be further increased by promoting self-care. Therefore, the potential increase in economic magnitude of self-medication was calculated. Through responsible self-medication supported by an adequate health policy, further resources and significant efficiency reserves for healthcare systems as well as national economies can be released. The resources freed up through an adequate self-care policy can play a significant role in building more resilient healthcare systems across Europe. In the light of these findings, it can be stated in general terms that from a clinical and health economic perspective, it is on the one hand counterproductive if people treat themselves or do not get treatment at all even though medical therapy would be required. On the other hand, it is likewise uneconomical and, moreover, counterproductive from the viewpoint of community and social interests if people visit the GP although self-medication would be sufficient. The latter is the case because these patients use resources (e. g. GP time) that could be used more efficiently for other purposes. Therefore, the aim of health policy should be to promote the right decision made by the individual in favor of treatment by a GP (if necessary) or in favor of responsible self-medication (if sufficient).

This new evidence should be used to support the development of national or European policy recommendations. Across Europe, new information and incentive systems for consumers would be required in order to leverage the efficiency reserves identified in this study. There is a strong need for further research and incentive systems throughout Europe that are adapted to the individual situation of each country. In consideration of the significant effects of self-medication on indirect costs, however, a stronger focus should be placed on self-medication not only from a health policy perspective but also from an economic policy perspective.

Conflict of Interests

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