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In collaboration with Christoph Baumgärtel

# Potentials and Opportunities for OTC-Switches in Austria

Data and Findings for the Support of Decision-Making  
by Companies and Politicians



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# 1 Introduction

## 1.1 Background of the Project

In 2013 the relevance of OTC medicines for the Austrian health care system was scientifically examined by a comprehensive study project. One of the findings of this project was that every Euro being spent on non-prescription medicines by consumers saves an average of five Euros in direct costs to the health care system.<sup>1</sup> To date, there is hardly any proactive promotion of the economic conditions for the OTC market, including strengthening of self-care, in Austria. This must be criticised with a view to the results of the study. Recognising the state of scientific knowledge concerning the importance of self-care for society, which has been generated not only in Austria but also in other countries, the health ministers of the twenty major industrial nations of the world state: *“The G20 members should (...) adopt policies that improve access to healthcare by establishing a pro-innovation ecosystem that prioritizes self-care and empowerment of individuals.”*<sup>2</sup>

One promising measure for the promotion of personal health responsibility is the improvement of information for patients about health and self-care related topics, combined with greater access to non-prescription medicines. As can be observed in international surroundings, Rx-to-OTC-switches (“switches”) can provide important incentives to the OTC market and exert positive effects on consumers, health care professionals and the public health care system, as well as OTC manufacturers. With this background, the cited health economic study project of 2013 has acknowledged switches as one of the most important building blocks for the promotion of self-care in Austria. The president of IGEPHA, Mag. Dr. Gerhard Lötsch, who is also a member of the Austrian Commission for Compulsory Prescription, admits: *“There are only single cases which qualify Austria as a switch-avantgarde nation.”*<sup>3</sup>

With a view not only to this challenge but also contrary endeavours from, for example, Austrian physicians, there should be an in-depth evaluation of the potentials, opportunities and possible risks of enhanced switch activities in Austria. This would enable a fact-based discussion and provide a sound basis for decision-making by OTC manufacturers. This project is a follow-up of similar initiatives that had already been implemented by Mag. Dr. Gerhard Lötsch at the beginning of the 1990s as a list of proposed switch candidates.<sup>4</sup>

<sup>1</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

<sup>2</sup> B20 Health Initiative (2017): Stepping Up Global Health Towards Resilient, Responsible and Re-sponsive Health Systems. Internet: [https://www.b20germany.org/fileadmin/user\\_upload/B20\\_Health\\_Initiative\\_Policy\\_Paper.pdf](https://www.b20germany.org/fileadmin/user_upload/B20_Health_Initiative_Policy_Paper.pdf) (Accessed: 16.11.2017).

<sup>3</sup> IGEPHA (2017a): Festschrift, 50 Jahre IGEPHA. Wien 2017. p. 34.

<sup>4</sup> Cf. IGEPHA (2017a): Festschrift, 50 Jahre IGEPHA. Wien 2017. p. 33.

## 1.2 Objective and issues addressed by this project

The overarching objective of this project is to promote the significance of self-care and personal health competence in Austria by the implementation of further Rx-to-OTC switches. This project shall contribute to this promotion, identifying switch potentials for indication areas and groups of active ingredients, and assessing the opportunities and risks of such switches. Within the evaluation, particular focus shall be placed on the views, needs and interests of the respective stakeholders. Besides care and safety aspects from the perspective of patients, the study especially targets the economic and real concern and the role of the market players. The examined perspectives include those of the patients, physicians, pharmacists and OTC manufacturers as well as the public health care system.

The results of the study shall support Austrian OTC manufacturers in their practical decision-taking and provide argumentation towards third parties in favour of switches planned by them. This argumentation relates to the medical and pharmaceutical risk-benefit discussion as well as argumentation in terms of business economy, socioeconomy and health policy. With the background of the above-described objective, the following questions are examined in detail in this research project:

- What is the current situation concerning switches and the spectrum of medicines which are available without prescription in Austria, and how can this situation be assessed in comparison with the international situation?
- Which potential new non-prescription active ingredients and indication areas can be identified for Austria in light of this comparison?
- Which legal, non-legal and societal framework conditions (switch climate) determine the chances for successful Rx-to-OTC switches? How can these factors currently be assessed in Austria and where might there be a need for action?
- What additional turnover potentials could be derived from this for pharmaceutical manufacturers and other actors in the OTC market? How far might these potentials accrue from the substitution of Rx medicines? Can switches open up completely new turnover potentials?
- What advantages and benefit potentials could be created by switches and the resulting extended opportunities for self-care?
- How can these aspects be assessed from the perspective of different stakeholders (especially manufacturers, health care professionals, patients)? What is the overall assessment from the perspective of health policy, health economy and society?
- How can, on the other hand, potential risks which might emerge from switches be assessed from a medical and pharmaceutical perspective? What is the status of evidence concerning this aspect?

- What practical conclusions can especially be drawn by pharmaceutical manufacturers from this analysis and how can the results of this study be used for the preparation and implementation of further switches?

## 1.3 Methods and Approach

The assessment of the switch situation in Austria, and the deduction of switch potentials, are based on comprehensive data analyses of the international situation concerning the prescription status of potential OTC substances as well as an evaluation of relevant studies and literature. The next step covers the definition of criteria for the prioritisation of the identified gaps for substances and indication areas, and the development of an operational procedure for the implementation of these prioritisation criteria. From this, a concrete list of proposed switch candidates for the Austrian market is derived. The conclusions drawn for Austria take the national framework conditions into account, including socio-economic and socio-demographic conditions, pharmaceutical law and further regulatory provisions, as well as the characteristics of the health care system. For the evaluation of the opportunities and risks of switches the current state of scientific knowledge and available empirical data are further taken into account. It uses the methods and standards of evidence-based medicine as well as health economy.

The retrieved empiric, demoscopic and economic data were supplemented by specific market research data which were collected for this particular project. For this purpose a representative consumer survey on switch-related topics was conducted in cooperation with the market research institute GfK, using a standardised questionnaire which was developed for this study. In addition, a questionnaire was developed for the manufacturers in order to collect the views and expectations of OTC manufacturers concerning switches.

The perspective-adjusted analysis of the results of our study is based on the economic calculation of the effects resulting from the switches. Furthermore, non-monetary consequences as well as existing and new appraisals generated from the surveys of consumers and manufacturers are included in our considerations.



## 1.4 State of Research Relating to the Topic “Switch” in Austria

On an international level, a series of studies examining the health economic potentials including cost saving potentials by switches has been conducted in the last 20 years.<sup>5</sup> Relevant references for Austria include an older study by Theurl and an up to date study on behalf of the Austrian Association of Pharmacists.

The study by Theurl which was conducted by the University of Innsbruck in 1998 explicitly deals with the health economic effects of the exploitation of switch potentials.<sup>6</sup> In the first step the author identifies switch areas and then switch candidates (i.e. medicines) in the Austrian pharma market. Assuming a maximum switch potential and resulting maximum cost savings of ATS 1.424 billion, the article further considers the likelihood of realisation of this switch potential.

The author assumes that for the examined switch areas an average of 50% of the potential could be realised, corresponding to a cost-easing effect amounting to about ATS 712 million. Theurl comes to a similar result based on the alternative assumption that there is a realisable switch potential amounting to 5% of the total spending on medicines in Austria. The calculated about ATS 800 million as well as the above-calculated sum have to be diminished by about ATS 120-150 million for eventual deficits from deductibles. The author also discusses the savings in physician costs based on lump assumptions. The study presumes that 10% of the approximately 35 million physician contacts per year (i.e. 3.5 million cases) could be avoided by self-medication. Based on average costs of ATS 552 per case honorary savings amounting to ATS 350 are presumed for every case of minor self-medication. Extrapolation of this calculation results in cost savings of about ATS 1.225 billion, i.e. 3.5% of the annual spending of the insurance companies in this service sector. According to Theurl the total cost saving effect for the insurances amounts to ATS 1.9 billion, i.e. 2% of the total annual expenditures for all service sectors.

In addition to these direct costs, the study also considers the savings for the national economy. The loss of economic productivity due to avoidable physician consultations is calculated on the basis of average gross salaries. It is further assumed that every second physician consultation relates to an employed insured person requiring absence from work. This absence (travel time, waiting time, treatment time) is assumed to correspond to an average duration

of 90 minutes. The described presumptions translate into about ATS 1.575 billion of losses of economic productivity which could be avoided by self-medication. The latter figure and the savings of physician costs sum up to a total annual saving potential of ATS 2.8 billion for the national economy.<sup>7</sup>

The results calculated by Theurl react sensitively to changes to his hypotheses. This applies particularly to the central assumption of a switch potential of 50%. For example, according to observations in Sweden, even those switches that were actually realised only led to a reduction of prescriptions by 26%.<sup>8</sup> There needs to be some discussion as to what extent there are plausible reasons in favour of a higher switch potential in Austria. On the other hand, the study does not claim scientific accuracy in terms of quantitative statements, but rather wants to create a basis for discussion of the economic aspects and effects of self-medication. In this sense these calculations, including those of the economic costs, provide a valuable contribution to the discussion of possible savings through switches.

A second noteworthy study on the potentials of an increased share of self-medication in Austria was conducted in 2010 by the Institute for Pharmacoeconomic Research (IPF).<sup>9</sup> This study also quantifies the realisable saving potentials of direct costs through avoidable physician consultations as well as indirect costs through savings of work time losses. It proposes two scenarios of an enlarged self-medication market. Scenario 1 presumes a realisable volume of switches amounting to 5% of the reimbursed packages of medicines. Under scenario 2 OTC products would additionally no longer be reimbursed by insurances, meaning that the sector of “OTx products” would vanish completely. Estimation of the effects on national economy is performed with the aid of a Budget Impact Model. For scenario 1 the IPF study derives a saving potential of EUR 433.48 million. Concomitantly private health expenditures would increase by EUR 72.58 million. Under scenario 2 the savings potential amounts to EUR 740.41 million and the increase of private health expenditures to EUR 128.37 million. These results are based on IMS Health data on annual reimbursements of Rx- and OTx-packages. The calculated substitution volumes total 7.6 million packages under scenario 1 and 13.44 million packages under scenario 2. The numbers of substitutable packages of medicines serve as the basis for the calculation of the amount of avoided physician contacts. For this calculation the study presumes an average number of 1.29 prescribed medicinal packages per physician contact.

The study integrates data from a study in Austrian pharmacies which showed that 17.6% of the self-medication cases were associated with health problems which lead to repeated vis-

<sup>5</sup> The majority of studies was conducted in the 1990s-era until the beginning of the 2000s-era. An overview of these studies can be found in May, U. (2002): *Selbstmedikation in Deutschland: Eine ökonomische und gesundheitspolitische Analyse*. Stuttgart 2002. Page 140 ff. & AESGP: *Encouraging self-medication can reduce the health care cost burden*. Brüssel 1998.

<sup>6</sup> Cf. Theurl, E. (1998): *Volkswirtschaftliche Aspekte und Effekte einer Verstärkung der Selbstmedikation in Österreich*. Innsbruck 1998.

<sup>7</sup> Cf. *ibid.*, p. 26.

<sup>8</sup> Cf. Carlston, A., Wennberg, M., Bergendal, L. (1996): *The influence of RX-to-OTC-changes on drug sales. Experiences from Sweden 1980–1994*. In: *Journal of Pharmacology and Therapy*. 21 (6). Rockville Pike 1996. p. 423–430.

<sup>9</sup> Cf. Institut für Pharmaökonomische Forschung (2010): *Der Selbstmedikationsmarkt in Österreich*. Wien 2010.

its to pharmacies. 90% of these cases were able to be resolved in the pharmacy. Only 10% required a physician consultation. These physician consultations are also included in the IPF study. The study further comes to the conclusion that the avoided physician consultations correspond to 227,000 (scenario 1) or 397,000 (scenario 2) avoided work day losses. 160,500 avoided sick leaves with an average duration of two days further prevents losses amounting to 321,000 working days. Following calculations based on data from the health insurances and IMS Health, the study estimates costs of EUR 102 for every lost work day, resulting in potential economic savings of EUR 55.92 million (scenario 1) and EUR 73.27 million (scenario 2) respectively.

The study sees itself as the basis for further examination of the market potential of self-medication. However, the model calculation is suited to provide information on the magnitude of the economic benefits of an increased share of self-medication. Nonetheless, the study stresses that therapeutic success must underlie the implementation of expanded self-medication.<sup>10</sup>

In the context of an examination of the health economic significance of self-medication in Austria, the authors of this study have described a simplified scenario with the aim of illustrating the potential magnitude of the effects of switches. Starting with the many experiences gained in other European countries concerning the impact of Rx-to-OTC switches on the development of sales of prescribed medicines and those purchased by the consumers, the following example calculation was carried out:<sup>11</sup>

Firstly, it was assumed that an extension of the spectrum of non-prescription substances could increase the extent of self-medication in Austria (in relation to physician consultations) by 15%. It should be noted that important groups of active ingredients, such as the triptans, are currently fully under prescription in Austria. With reference to the model calculation performed in the study of 2013 prescriptions would decline by approximately 11 million packages with a value of EUR 170.5 million, provided that 15% of physician cases were substituted by self-medication. The corresponding net relief for health insurance would equal nearly EUR 134 million after deduction of the prescription fee.<sup>12</sup> For the OTC market in Austria, this scenario would involve an increase by around 10 million packages to around 75 million packs per year.<sup>13</sup>

<sup>10</sup> The preceding description of the state of studies is based on respective statements in May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

<sup>11</sup> Cf. For justification of this scenario, also in relation to OTC use in the international comparison: IGEPHA: Selbstmedikation Heute – Morgen. Status und Potential für Selbstmedikation in Österreich. Ergebnisse Marktforschung. Wien 2010.

<sup>12</sup> Cf. also the substitution scenario of Theurl: Based on the broad assumption that further 5% of the total pharmaceutical market in Austria could be transferred to self-medication through switches, the author comes to results of a similar magnitude.

<sup>13</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

In addition to these switch studies related to Austria, there are a number of further international studies which quantify the potential of switches with reference to individual countries and active substances/medicines. As far as the knowledge obtained from these studies is transferable to the Austrian situation, they are incorporated into the considerations of the present study.<sup>14</sup> For example, one noteworthy study by Cohen et al. (2013) examined 12 publications from the United States and Europe on the subject “switch” for various indications. Cost savings for payors and patients were detected in 75% of these publications.<sup>15</sup> Another six studies, having been identified by Karay et al. (2011), explore the economic potentials of switches. They examined primarily the situation in the United States with reference to antifungals, antihistamines and omeprazole. These studies likewise identified savings due to the elimination of reimbursements as well as further cost reductions, for example through a lower extent of sick-leaves.<sup>16</sup>

<sup>14</sup> An overview of the state of studies until 2004 is given in the AESGP publication “The Economic and Public Health Value of Self-Medication”, Brussels 2004. This publication also includes a simplified model for the calculation of the effects of a 5% substitution of prescriptions by self-medication in Austria. According to this calculation social insurance can save about EUR 138 million. The total volume of savings including the costs for the national economy shall amount to approximately EUR 230 million.

<sup>15</sup> Cf. Cohen, J., Millier, A., Silva, A. N. (2013): Assessing the economic impact of Rx-to-OTC switches: systematic review and guidelines for future development. In: J Med Econ 2013; 16: pp. 835–844.

<sup>16</sup> Cf. Karay, S., Plich, A., Flostrand, S., Toumi, M. (2011): The economic impact of switches of prescription drugs to the over-the-counter Status (rx-to-OTC): a systematic literature Review, ISPOR 14th Annual European Congress, Madrid, Spain, 5–8 November 2011.



## 2 Significance of Self-care and Switches in Austria

The following sections highlight the topics “Self-care” and “Switches” in a common context and thus describe the motivation of the authors to address these topics with special focus on Austria.

### 2.1 The Importance of Self-care for Patients and the Health Care System

As a result of demographic change and medical/pharmaceutical progress the Austrian health care system faces serious financial challenges. Public health approaches based on a strengthened personal responsibility represent one partial way out of this economic and political dilemma. With regard to the supply of medicines this implies the promotion of the significance of the treatment and prevention of minor ailments under personal responsibility with non-prescription (so-called OTC) medicines. As OTC medicines can typically be administered without prior medical consultation, this form of self-care can spare time capacities and resources in the field of outpatient care and at the same time save costs for prescribed medicines. From the economic perspective it is particularly relevant that the use of OTC medicines regularly leads to cost reductions and increased efficiency through preventive effects, as well as reduced losses of working time and productivity losses. The patients themselves particularly appreciate the direct and convenient access to treatment, as well as time savings.

In 2013, the significance of OTC medicines for health care in Austria was scientifically examined in the context of a comprehensive study project. This study substantiated the above-described aspects with concrete data. According to the data, every Euro that is spent on self-purchased non-prescription medicines in Austria saves an average of about EUR 5 in direct costs to the health care system. Not using this form of health responsibility would mean additional direct costs amounting to EUR 2.3 billion for health insurance companies. This would be accompanied by more patients needing to visit physician offices, reflected by an additional 13 million physician hours, a burden which could not be borne by the medical profession and the health care system. Figure 1 illustrates the cost saving effects of self-medication:

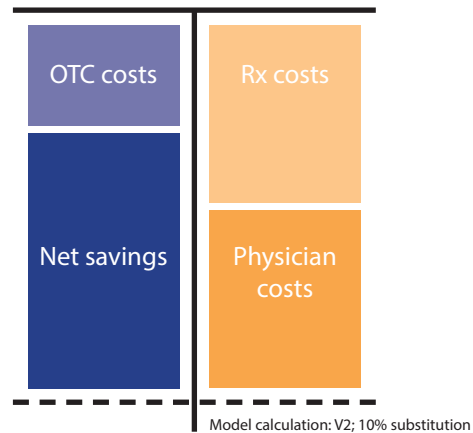


Figure 1: Savings of direct costs by self-medication<sup>17</sup>

From the individual consumer perspective, consideration of intangible effects, particularly time and travel costs, can be decisive when making a choice for self-care. Whereas for a pharmacy visit an average of 22 minutes must be discounted including travel time and service time in the pharmacy, a combined physician and pharmacy visit requires an average of 85.5 minutes in Austria.

How a person appraises this time gain of more than one hour in the case of self-medication and sets it in relation to the additional financial expenses from his own purse, is individually very different. Last but not least it may depend on whether the time needed for the visit is taken from the spare time of the patient or from his work time, and whether an employed worker connects the physician consultation with the prospect of a certificate of incapacity for work. From the economic perspective, it is significant that personal time expenditures of patients are often accompanied by losses of working time, caused by the time for the physician consultation and sometimes unnecessary sick leaves. Without self-medication to the extent practiced in Austria today the additional therapy- and leave-related losses of working hours would amount to a value of about EUR 730 million per year.

These considerations are of special relevance with a view to the objective of a “medically and economically justified shift of services (from the full inpatient sector) to the day hospital or out-patient sector” on the one hand, as stipulated by the Austrian health care reform in 2012, as well as the further shift from the outpatient sector to the general practitioners sector on the other hand. The result is an additional demand for outpatient and general practitioners medical services, which can be freed up by the promotion of health responsibility.

<sup>17</sup> May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

Although the status quo analysis reveals that pharmacy-based self-medication currently already plays an important role for health care in Austria, the de facto importance of OTC medicines in Austria and their acceptance by professionals, the population, policy and health insurance still lags behind the importance which is dedicated to medicines for self-care and their use in comparable countries today.

With a view to this finding, the Austrian health care system offers various starting points for further promotion of the willingness and ability of the population for self-care of minor ailments. In this way, additional efficiency and profitability reserves could be exploited by an extended scope of self-care.

## 2.2 Switches for the Promotion of Self-care

The availability of suitable non-prescription substances is a prerequisite for self-medication to be possible in the respective indication areas. Therefore Rx-to-OTC switches are naturally a suitable tool for the promotion of self-medication. This basic importance of switches for the promotion of self-care is also reflected in the results of a survey of experts.<sup>18</sup> For this survey, representatives from institutions, politics, associations, science and market research, with particular expertise in the sector “Self-care and pharmacy”, were interviewed in guidance-supported personal interviews. All measures which have been identified in literature as relevant for the promotion of self-care were presented to the experts with the request to assess them in terms of their suitability and feasibility. The following Figure 2 graphically summarises the individual assessments of the tool “switch”:

<sup>18</sup> Cf. May, U., Bauer, C. (2016): Selbstbehandlung und Apotheke. Gutachten im Auftrag des BAH. Bonn 2016.

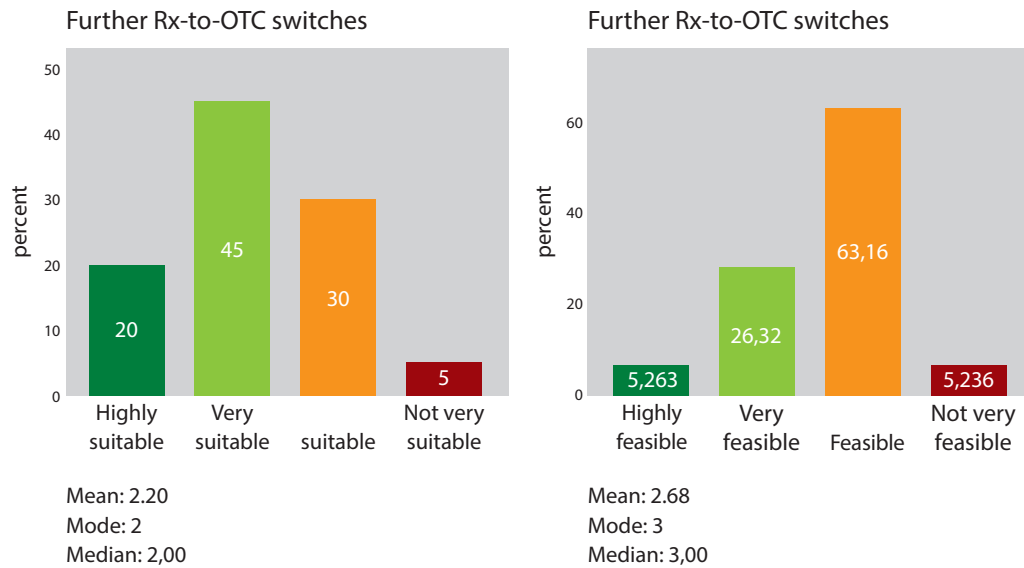


Figure 2: Expert assessment of switches for the promotion of self-care (suitable/feasible)<sup>19</sup>

As a result, on the basis of a school grading system from 1 to 5, suitability of switches was rated with a mean grade of 2.2. The most frequently awarded grade (the mode) and the median both had a rating of 2.0. This shows that the positive assessment of switches was relatively unanimous and that switches – unlike some other tools for the promotion of self-care – are not associated with a polarisation of expert opinions. The feasibility of switches was assessed with some differences, but was still positive. Polarisation was a little bit stronger with some individual experts considering switches as “highly feasible” and others as “not very feasible”.

The integration of this expert assessment of switches within the context of other assessments of proposals to promote self-care is summarised in Figure 3. It demonstrates clearly that switches belong to the preminent tools for the promotion of self-care, both in terms of their suitability as well as their feasibility, especially when compared to alternative options.<sup>20</sup>

<sup>19</sup> The Figures reflect the results of the expert survey in the form of school grades. The left-hand figure shows the experts opinion on the suitability of switches for the promotion of self-medication and the right-hand figure their assessment of feasibility of the switches. The assessment comprises the respective alternative statistical means (arithmetic means), the mode (most frequently given value) and the median (value such that equal numbers fall above or below it). Cases with significantly varying statistical means are described as a polarisation of answers. This is particularly not applicable to the suitability of the switches for self-medication, or to their feasibility. From this it can be concluded that the attitude of experts towards “switches” polarises slightly at best

<sup>20</sup> As a restriction it must be noted that the majority of persons included in the cited survey were experts practicing in Germany. However, all have international experience and market insights. In addition, there are no indications why respective experts from Austria – irrespective of possible conflicts of interest – might come to significantly divergent assessments.

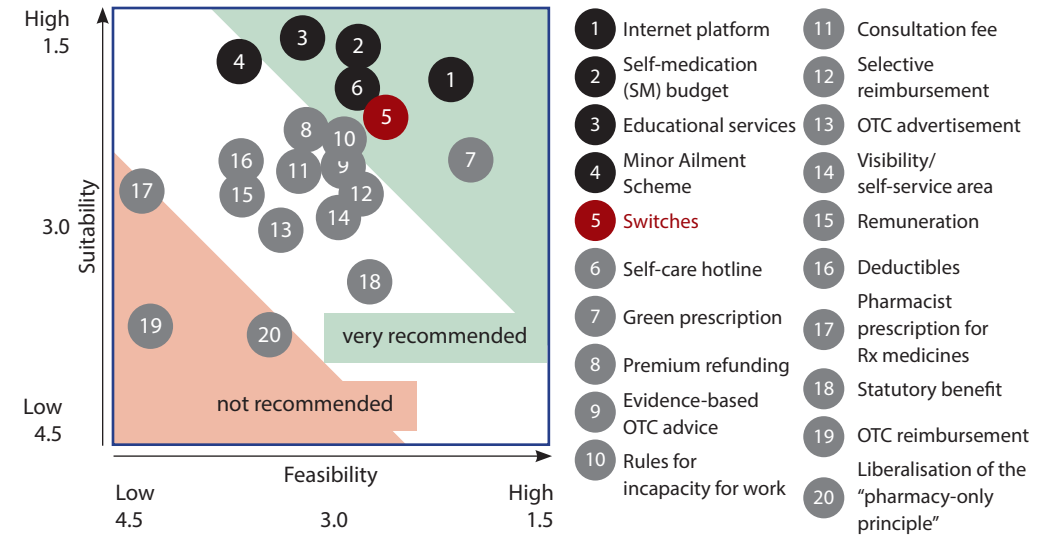


Figure 3: Expert assessment of measures for the promotion of self-care<sup>21</sup>

The potential for expansion of self-care beyond the existing scope and importance can essentially be identified in only two ways, by either facilitating access to a greater number of people in already established areas of self-care, or by adding new indication areas where self-care has not been practiced so far. In the first case, self-care becomes more profound by exhausting its potential within the given opportunities. In the second case, the scope is enlarged by extending the range of indications accessible to self-care. Of course, both trends of development occur simultaneously and in parallel in practice, so that proportional growth of self-care is imaginable in terms of “depth” and “breadth”. Figure 4 schematically summarises these growth scenarios and Austria’s current position in relation to potential opportunities for development. The arrangement of the status quo in the left-hand and bottom sectors of the coordinate system demonstrates that for both depth and breadth there are considerable development potentials in Austria and that these potentials are disproportionate in terms of scope, i.e. with regard to new applications. This reflects the relatively low availability of non-prescription substances, as presented below in detail.

<sup>21</sup> May, U., Bauer, C. (2016): Selbstbehandlung und Apotheke. Gutachten im Auftrag des BAH. Bonn 2016.

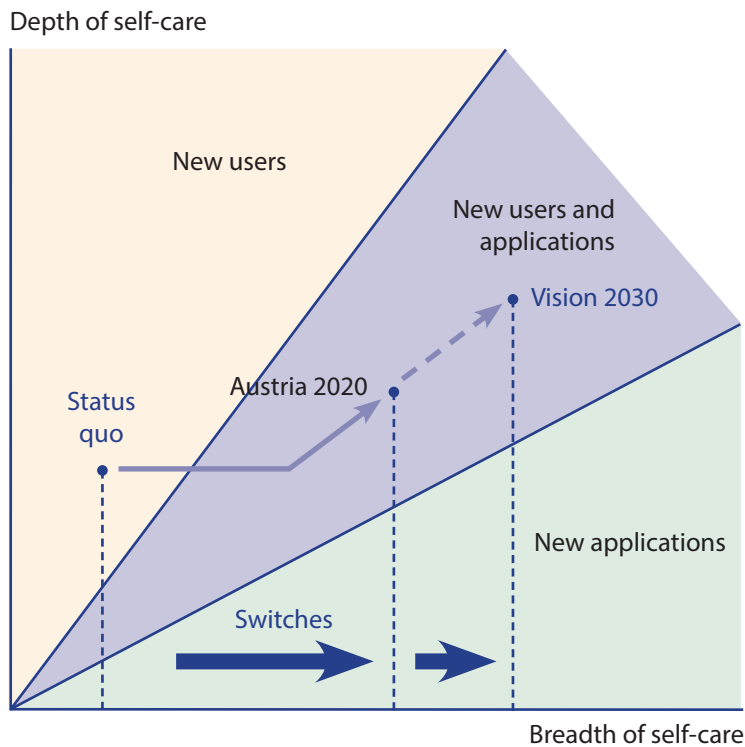


Figure 4: Development potential of self-care by new users and new applications

One potential way to increase the depth of self-care would be to reduce the number of current physician treatments of minor ailments in favour of self-care. A second potential method for winning new users for pharmacy-based self-care could be in the area of previously untreated minor ailments. This means that self-care could attract further clientele and gain more growth impulses from the large number of cases in which so far treatment has been completely omitted (therapeutic nihilism) or where it has not reached the threshold for pharmacy-based self-care.<sup>22</sup> Rx-to-OTC switches could exert a “deepening” effect on both currently physician treated and untreated health problems. However, this can only work in so far as creating more simple, more effective, safer, or more user-friendly opportunities for self-care in indications which were previously already generally accessible to self-care. In this sense, the “substance gaps” identified in Chapter 3.1.2 for Austria, are also important as well as of health economic interest, if they lie in areas where OTC medicines already exist.

Above all, switches are the classic instrument for the extension of the spectrum of health disorders which are accessible to self-care. The OTC switch of new substances and substance

<sup>22</sup> If and to what extent such kind of “optimised self-medication” can likewise open up economic and efficiency reserves for the health care system has not been scientifically investigated so far.

classes can be the initial step towards opening the door for self-care of entire indication-areas or partial indications for the first time. This is particularly true if an OTC switch provides the first adequate treatment option with non-prescription medicines in a specified indication area. For such cases, a series of examples can be found in the international switch history of the last few decades. They include aciclovir for herpes (1992), clotrimazole for vaginal mycosis (1994), nicotine for smoking cessation (2000) and miconazole for the treatment of fungal diseases of the oral cavity (2005). During the last 15 years the lipid-lowering drugs lovastatin and simvastatin were switched in Canada and the UK respectively, and the antiviral agent valaciclovir was switched in Finland for systemic use against labial herpes.<sup>23</sup>

In some cases it is even possible that the non-prescription status of certain medicines, or a certain therapeutic indication, now cater for an indication area or a group of medicines being perceived by the consumers as being of significant practical relevance for the first time. One example of this phenomenon is the nicotine-containing medicines for smoking cessation therapy. As so-called lifestyle-medicines, these medicines are excluded from reimbursement by statutory health insurance in many countries, with the result that they de facto do not play a role in medical prescription practice. Without the non-prescription status of these medicines there would be hardly any basis for their use in practice, particularly since direct-to-consumer advertising is not allowed for prescription medicines according to national advertising regulations.

Another recent example concerns ulipristal or levonorgestrel containing emergency contraceptives (“morning-after pills”). When they were switched to OTC status in Germany in 2015, one argument in favour of the switch was that a physician consultation might constitute a hurdle for the use of the pill in cases where their use would be indicated and that low-threshold access to the medication in pharmacies “would be desirable”.<sup>24</sup> This hurdle also existed in Austria. To make things worse, there were frequent reports of cases in which prescription of the pill was refused on “theological” grounds, despite the prescription being indicated. The morning-after pill was therefore switched to non-prescription status back in 2009.<sup>25</sup> This is one of the rare examples in which Austria has to date used the existing switch potential. After the OTC switch in Germany the number of packages of emergency contraceptives dispensed in pharmacies increased by an average of 30% across the federal states in a short period of time, before it stabilised at the resulting higher level.<sup>26</sup>

<sup>23</sup> Cf. AESGP (2017): Database OTC ingredients. Internet: <http://www.aesgp.eu/facts-figures/otc-ingredients/> (Accessed: 16.11.2017).

<sup>24</sup> Cf. Deutscher Bundestag (2014): Drucksache 18/2630. 18. Wahlperiode 24.09.2014.

<sup>25</sup> Cf. Bundesministerium für Gesundheit und Frauen (2017): Die Pille danach. Internet: <https://www.gesundheit.gv.at/leben/sexualitaet/verhuetung/verhuetungsmittel/notfallverhuetung/pille-danach> (Accessed: 29.11.2017).

<sup>26</sup> Cf. IMS Health (2015): Der Gesundheitsmarkt in Deutschland. Frankfurt 2015.

Cf. Bundesverband Deutscher Versandapotheken (2015): IMS HEALTH: Rezeptfreie „Pille danach“: Zweistellige Zuwächse der Abgaben in Bundesländern. Internet: <https://www.bvdva.de/aktuelles/news-kooperationspartner/71-ims-health-rezeptfreie-pille-danach-zweistellige-zuwachse-der-abgaben-in-bundeslaendern> (Accessed: 29.11.2017).

International switch experts have recognised an opportunity for the extension of the basis for self-care, beyond the described switch-opportunities in the classical sense, by opening up certain chronic diseases for self-care by patients after initial diagnosis by a physician. The Association of the European Self-Medication Industry (AESGP) has developed a proposal in this regard which is relatively far-reaching when compared with self-medication areas currently existing in European countries (see Figure 17). This proposal will be discussed in a subsequent Chapter on “visionary switch projects”, as it goes beyond minor ailments where the focus of self-care initiatives is traditionally placed and is thus only partly compatible with the original definition of self-care (which for example also includes self-diagnosis).

Direction	Depth / new users	Breadth / new applications
Potential	Treatment of minor ailments by physicians	New indications through switches
	Untreated minor ailments / prevention	Chronic diseases after initial diagnosis by a physician

Table 1: Depth and breadth of self-care

In conclusion, the role of switches for the promotion of self-care can be summarised as follows: The availability of non-prescription medicines is important for the quantity and quality of self-care. Rx-to-OTC switches can in particular provide important impetus for the growth of self-care, if they open up new indication areas or considerably improve the opportunities for self-care in a given indication. In addition, the availability of a non-prescription active substance can directly influence a patient’s decision in favour of or against a physician consultation. The situation in Austria with the rather restrictive “switch culture” can in particular be suggestive for the quantitative effect that can be associated with switches in terms of the volume of self-care.<sup>27</sup> As a restriction however, it must be noted that the expected quantitative effects of switches on the extent of self-care should be estimated with caution, because they cannot be assessed in isolation. Instead, it is deemed necessary that the existing environment of the self-care market in a respective country (“switch climate”) creates the economic breeding ground for the switched substances (see Chapter 4).

## 2.3 Criteria and Arguments for the Consideration of Potential Switches

Rx-to-OTC switches are embedded in complex considerations. There is a charged relationship on the one hand between the paternalistic consumer protection view and the right of self-determination of the individual and on the other hand between the care targets determined by health policy and an efficient use of resources financed on the basis of solidarity. The criteria applied to potential switches are derived from this charged relationship. A strict and unconditional “right of way rule” for purely safety aspects does not exist: The views of the individual, as well as those of society and political institutions, balance safety aspects against concurrent objectives under all circumstances. It could not be rationally justified to handle switches in a different way.

Prior to every switch, there must be an evaluation on the basis of the best available evidence whether a medical layperson will be able to treat a given indication regularly and safely with a given active substance by himself. Possible risks that could likewise emerge in connection with a physician consultation are to be balanced against this consideration. In addition, it has to be considered at what price additional safety, through the maintenance of the prescription status, could perhaps be purchased. For this economic evaluation the additional costs of medical treatment have to be balanced against potential self-care, including the cost of follow-ups caused by misuse of both treatment paths.

Besides these basic considerations that are applicable to normal switches, further very specific aspects have to be taken into account in certain cases, especially in the context of so-called innovative switches. These aspects may sometimes play a decisive role for the overall assessment. For example, in the case of migraine therapy low-threshold and fast access to care is a co-decisive factor in the choice of patients to be medically treated. This is in turn of great importance with a view to work and productivity losses. Simple access to vaccines without prescription, e.g. for the prevention of influenza, eventually combined with vaccination competency of pharmacies, can likewise be important, as it may distinctly elevate the vaccination rate of the population. Here, the focus of interest lies on the control of an epidemic and sometimes life-threatening disease incidence. In the case of the treatment of erectile dysfunction with sildenafil, the protection of patients against falsified products is an additional central argument for a switch, which would otherwise constitute a risk through the preferred route of purchase via the internet. In the case of the “morning-after pill” it was the time-critical emergency situation that argued for a waiver of the physician consultation. In the case of the switch of nicotine products for smoking cessation, the key aspect is and was that smokers de facto only use this proven to be effective and for society strongly cost-reducing medical

<sup>27</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

assistance if it is available without prescription. Special effects of this kind can, besides basic considerations, eventually be decisive factors within the societal decision-making in favour of a switch.

This short overview of the eligible criteria and the pros and cons of potential switches, which hereafter will be further discussed in detail in this expertise, reveals that the consideration of decisions on every envisaged switch must always be multidimensional. It depends on the substance and indication, and sometimes also on the conditions of a given health care system or country-specific characteristics.

## 3 Prescription Status and Switch Potentials

The focus of Chapter 3 lies on the current prescription status of medicines in Austria and the potentials for OTC switches resulting from this situation. The first step of analysis is an international comparison of the prescription status of medicines that are currently on the market. On this basis substance and indication gaps for self-medication in Austria shall be identified.

The second part of this Chapter deals with the description of criteria which can be used for prioritisation of potential switches (switch proposals). Based on the identified substance and indication gaps, and with the aid of the criteria for prioritisation, a procedure for operationalisation of the prioritisation criteria will be developed in the third part of this Chapter. From this, a concrete list of proposals for switch candidates for the Austrian market will be derived.

### 3.1 International Comparison

For various reasons the international comparison of the prescription status of medicinal substances represents an effective tool and reasonable first step for an approach to potential switches in Austria. A cursory preliminary examination immediately demonstrates that a number of substances are available without prescription in Europe and worldwide, whereas they are under prescription in Austria. In this context the regulatory situation in Austria can be considered as relatively restrictive. Extensive experiences with the OTC status of various substances are internationally available. These experiences relate to the risk-benefit situation in their practical application by the consumer as well as to further implications relevant for care and economic implications associated with these substances or switches. With regard to the comparison with other EU Member States, decisions on the prescription status are in principle based on the same regulatory criteria of pharmaceutical law which also apply to Austria. Formally, the switch of a substance in an EU country can therefore per se give rise to a respective evaluation in other Member States.



### 3.1.1 International Overview of Prescription Status

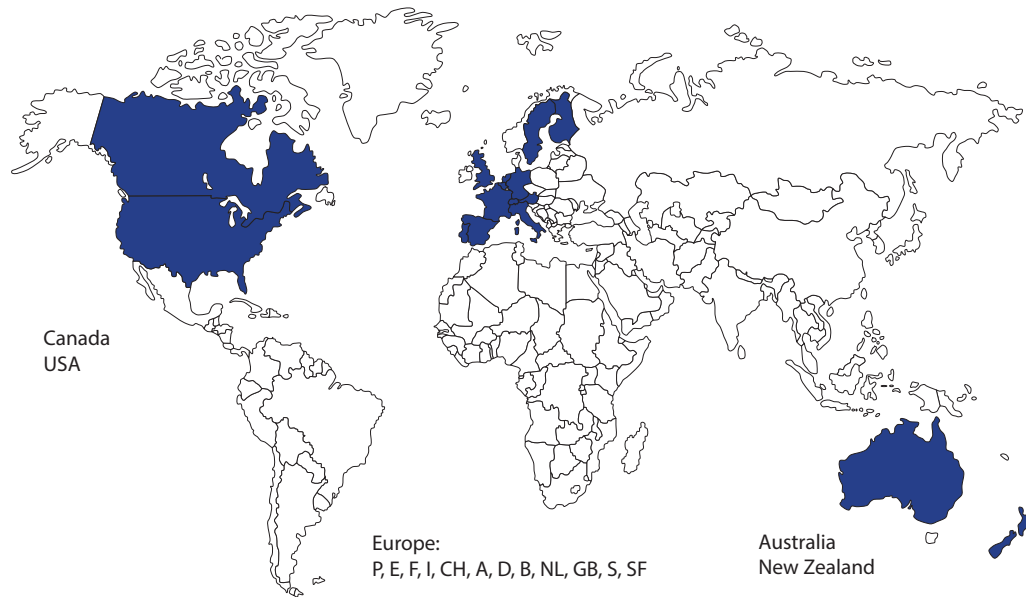


Figure 5: Reference countries for the analysis of switches

The international overview created for this project (Extract in Figure 6) is based on the database “OTC ingredients” of the AESGP<sup>28</sup> as well as the searches of the authors themselves.<sup>29</sup> In order to warrant maximum up-to-dateness of the data from Austria, which are of course of utmost importance for this expertise, an additional countercheck with the data contained in the Austrian Register of Medicinal Products (“Arzneispezialitätenregister”) was performed. This database is situated at the Austrian Agency for Nutrition Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit, AGES) that is acting on behalf of the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG).<sup>30</sup>

Where necessary, inconsistencies between the databases were corrected with reference to the Austrian Register of Medicinal Products.<sup>31</sup> Fifteen countries were included in the evaluation, among these were eleven European and four non-European countries. The country selection was made using various points of view. On the one hand, there are countries that have similarities with Austria in terms of socio-demographic and socio-economic characteristics,

<sup>28</sup> Cf. AESGP (2017): Database: OTC Ingredients. Internet: <http://www.aesgp.eu/facts-figures/otc-ingredients/> (Accessed: 16.11.2017).

<sup>29</sup> The information given in the AESGP Database „OTC Ingredients” was generally tested for plausibility. Accuracy of detailed information for all countries cannot be warranted.

<sup>30</sup> Cf. BASG (2017): Arzneispezialitätenregister. Internet: [https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?\\_afLoop=65486111406095481&\\_afWindowMode=0&\\_adf.ctrl-state=cjp9ziwnv\\_4](https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afLoop=65486111406095481&_afWindowMode=0&_adf.ctrl-state=cjp9ziwnv_4) (Accessed: 16.11.2017)

<sup>31</sup> Cut-off date for last check: 11.10.2017.

as well as ethnic and cultural roots. These include the neighbouring countries Italy, Switzerland and Germany. France, Spain and the United Kingdom were included as other European countries with a view to their size and the importance of the respective pharmaceutical markets. A number of smaller countries or markets, namely The Netherlands, Belgium, Finland and Sweden, were taken into account for the evaluation with regard to their advanced experiences with switches or the given switch climate or the importance of self-care. Using these criteria, Australia, New Zealand, Canada and the United States were included in the analysis as non-European countries (Figure 5).

The tabular overview including these 15 countries and a total of around 300 substances indicates the status of an active substance in the respective country by using different colours that stand for the following differentiation: non-prescription (green), non-prescription after switch within the past 15 years (light green), under prescription (red), under prescription after re-switch (light red), non-prescription with restrictions (yellow) and non-prescription with restrictions after switch within the past 15 years (light yellow).

The classifications in the above-described categories were made after careful consideration of each individual case. In particular, the restrictions in terms of availability (yellow category) were assessed pragmatically with regard to their actual relevance for the application by consumers. Substances that are not approved or not marketed in the country are highlighted in grey.<sup>32</sup> Figure 6 shows an exemplary extract from the Table:

	Australia	Austria	Belgium	Canada	Finland	France	Germany	New Zealand	Italy
Aluminium hydroxide	Green	Green	Grey	Grey	Grey	Green	Green	Green	Grey
Cimetidine	Green	Green	Red	Green	Grey	Green	Red	Green	Green
Pantoprazole	Light Green	Light Green	Light Green	Red	Light Green	Light Green	Light Green	Light Green	Light Green
Dicyclomine (Dicycloleverage)	Red	Grey	Grey	Green	Grey	Grey	Red	Red	Grey
Adenosine	Red	Red	Red	Yellow	Red	Green	Red	Red	Red
Ketoconazole (topical)	Green	Yellow	Green	Green	Green	Green	Green	Green	Light Green
Chlortetracycline (topical)	Red	Red	Green	Grey	Grey	Red	Red	Red	Red
Famciclovir	Light Green	Red	White	Red	Light Green	Red	Red	Light Green	Red
Triamcinolone	Green	Red	Green	Light Yellow	Yellow	Red	Yellow	Yellow	Yellow
Levonorgestrel	Light Green	Light Green	Green	Light Green	Light Green	Green	Light Green	Light Green	Red
Nicotine (gum)	Green	Green	Green	Green	Green	Green	Green	Green	Green
Mometasone (nasal)	Light Green	Red	Red	Light Green	Green	Red	Light Green	Green	Green

Figure 6: Exemplary extract from the table “Prescription status international”

<sup>32</sup> Table elements in white stand for cases in which the respective information could not be retrieved.

Summing up of the number of medicines that are available without prescription at the country level results in the following overview (Figure 7): There is a relatively large degree of fluctuation between the Anglo-Saxon countries New Zealand, Australia and Great Britain, the traditionally very liberal OTC countries, and The Netherlands at the opposite end of this comparison. With 76 non-prescription substances Austria reaches only half of the 149 OTC substances that are available as OTC in New Zealand. Across the comparison of the 15 countries, Austria is thus on the penultimate rank.

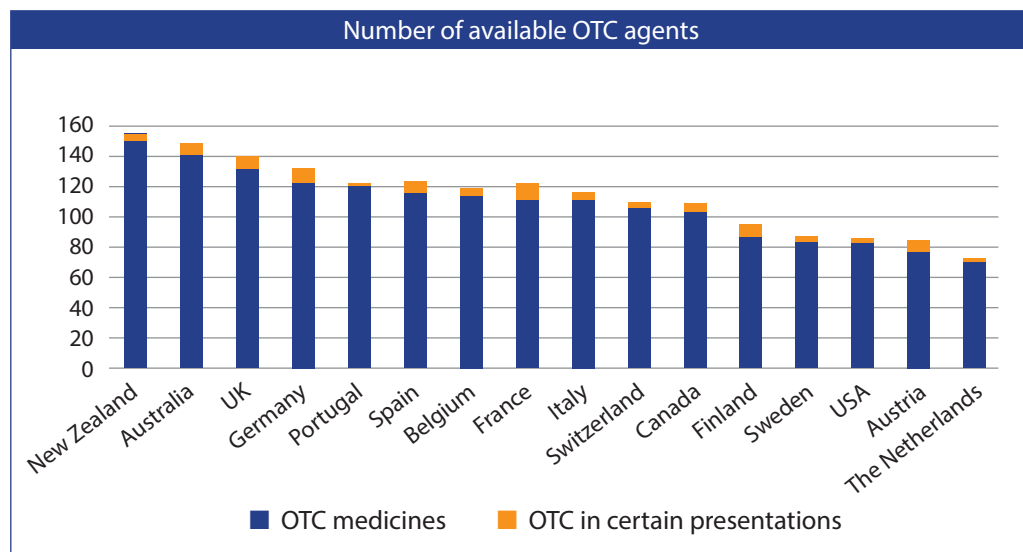


Figure 7: Number of non-prescription medicines on the national level

The number of substances which are under prescription in these countries is inverse to the number of substances with OTC status. The total of this number and the number of substances which are not available at all in a country reveals, which number of substances that are available as OTC in at least one country is not available for self-medication in a respective country (see Figure 8).

This illustration shows the particular dilemma for small countries where, due to low profitability for companies, many substances are not imported, marketed or switched. This aspect will be further discussed in the interpretation (Chapter 3.1.3).

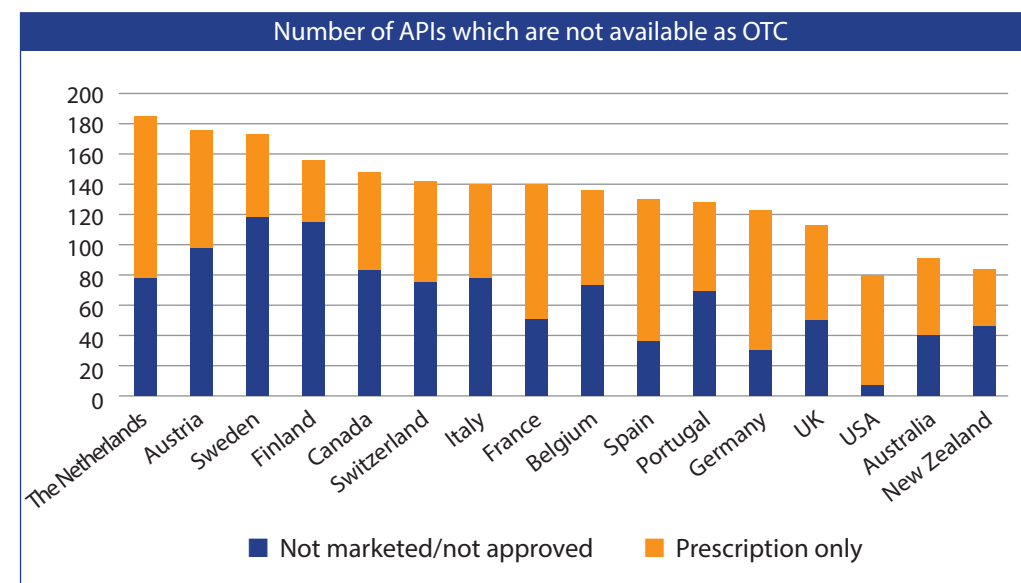


Figure 8: Number of medicines which are not available as OTC medicines at national level

### 3.1.2 Substance and Indication Gaps for Self-medication in Austria

According to the international comparison described above, in many countries there are numerous substances with OTC status that can only be dispensed in pharmacies upon presentation of a medical prescription in Austria. Within this expertise the term “substance gaps” in Austria shall mean that the respective substances are available without prescription in several, or even in the majority, of the countries included in the comparison. The significance of substance gaps is classified in three classes based on an ABC analysis, with reference to the number of countries in which they are available over-the-counter in Europe or “worldwide”. The quantitative requirements for classification in the classes A, B or C are given in the following Table 2.

Class / rank	Criteria
A	at least 8 countries worldwide, of these at least 6 countries in Europe
B	at least 5 countries worldwide, of these at least 3 countries in Europe
C	at least 3 countries worldwide, of these not necessarily one in Europe
Without ranking	active ingredient is OTC in less than 3 countries worldwide

Table 2: ABC Analysis of the significance of substance gaps across countries

The highest priority is assigned to substance gaps where the active ingredient is available without prescription in more than half of the included European countries as well as in more than half of the countries of the worldwide selection. For obvious reasons, particular emphasis was placed on the European perspective. The following overview (Table 3) classifies the substance gaps identified for Austria in accordance with the above-mentioned prioritisation criteria. Those substances that are OTC in less than three reference countries of the international comparison have not been proposed as switch candidates for Austria. Within this expertise, the term “indication gap” shall mean that an entire indication, or a relevant part, does not include any substances from the OTC sector, as respective non-prescription substances are not available in Austria.

Class / rank A	Class / rank B	Class / rank C
Benzyl benzoate (topical)	Bacitracin (topical)	Azelaic acid
Cinchocaine (topical)	Cimetidine	Budesonide (nasal)
Diclofenac (oral)	Codeine	Chloramphenicol
Doxylamine succinate	Diphenhydramine	Desloratadine
Ephedrine	Diphenylpyraline	Dihydrocodeine
Glucosamine	Econazole (vaginal)	Estriol (vaginal)
Hydrocortisone (topical)	Ketoprofen	Famciclovir
Naproxene	Lansoprazole	Fenticonazole (topical)
Piroxicam (topical)	Mebendazole	Fluconazole
	Mometasone (nasal)	Levocetirizine
	Neomycin sulphate	Metoclopramide
	Noscapine	Metronidazole (topical)
	Nystatin	Sumatriptan
	Polymyxin B (topical)	Theophylline
	Prilocaine	Triamcinolone
	Pyrantel	Ubidecarenone
	Sucralfate	

Table 3: Substance gaps in Austria

### 3.1.3 Interpretation and Assessment

The availability of an active substance without prescription in other countries is not per se taken as a sufficient reason to recommend an OTC switch for Austria. However, the substance gaps provide important indications as to which ingredients have internationally proven their robustness in scientific and pharmaceutical regulatory assessments with regard to their non-prescription status. Furthermore, in view of the number of countries where a medicinal product has OTC status, experience with the practical use of the substances in the market increases, including an increasingly wider range and greater variety of surroundings in terms of consumers and diverging national systems. With this background, the substance gaps and their expression have important implications with a view to the suitability of a substance under risk-benefit aspects. The prioritisation based on the substances gaps is therefore also included in the subsequent discussion of the switch candidates under risk-benefit aspects.

Indication gaps can result from the accumulation of substance gaps in one indication area, so that even in certain health problems and indication areas which are in principle accessible to self-care, such self-care can de facto not take place or only take place insufficiently (*breadth of self-medication*). Where the international overview of prescription status has revealed such indication gaps, this provides a definite suggestion regarding the relevance of potential switch candidates for care. In this respect the identified indication gaps are immediately incorporated into the assessment of the relevance for care which is performed below (Chapter 3.2.2).

A special problem occurs if there is no marketing authorisation for a substance or if it is not marketed. The evaluation of the number of internationally available prescription substances<sup>33</sup>, as well as substances which are not imported or marketed in the countries, reveals a particular dilemma for small countries. Due to low profitability they are not imported, marketed or switched by the companies in such countries. The distinct (statistically significant) correlation between the size of a country (or market) based on the number of inhabitants and the number pharmaceutical substances that are not available in the respective country is illustrated in Figure 9. It is obvious that this relationship is not only statistical, but also causal.

In many countries switch procedures are to be initiated by pharmaceutical companies and introductions to the market are also driven by manufacturers. It should therefore be discussed how far procedural changes or financial incentives could be useful and necessary in order to promote such activities (see Chapter 4). Last but not least the exploitation of existing substance gaps (see Table 4) may have a similar effect on the self-care sector as Rx-to-OTC-Switches.

<sup>33</sup> The illustration only covers a selection of active ingredients included in the AESGP database, i.e. substances having an OTC status in at least one country covered by the AESGP database.

Acrivastine	Dicyclomine (Dicycloverine)	Neticonazole (topical)
Alclometasone (topical)	Diflunisal	Nicotine (Nasenspray)
Almotriptan	Dimemorfan	Niflumic acid (topical)
Alverine	Diosmectite	Nifuroxazide
Antazoline	Dyclonine (oral)	Nizatidine
Azatadine	Ebastine	Loxoprofene sodium hydrate
Beclomethasone (nasal)	Felbinac (topical)	Orciprenaline
Benproperine	Flavoxate hydrochloride	Oxatomide
Benzonatate	Flubendazole	Oxetacaine
Benzyl benzoate (topical)	Flunisolide (nasal)	Oxiconazole
Bromhexine	Sodium fluoride	Oxitriptan
Brompheniramine	Fluticasone	Paracetamol + Dihydrocodeine
Bronopole	Fusafungine	Phenazopyridine
Bufexamac (topical)	Haloprogine (topical)	Podoflox (Podophyllotoxin)
Butenafine	Hyaluronic acid (topical)	Pramocaine
Butoconazole	Hymecromone	Prochlorperazine
Butylamino benzoate	Idoxuridine (topical)	Promethazine
Carbenoxolone	Idrocilamide	Propantheline
Carbinoxamine	Isoconazole (vaginal)	Propionate Ca+Na (vaginal)
Carbocisteine	Potassium nitrate (toothpaste)	Pyritinol
Carnidazole	Lindane (topical)	Quinfamide
Cetraxate	Lodoxamide	Silver sulfadiazine 1%
Chloroxylenole	Loxoprofene sodium hydrate	Strontium chloride (toothpaste)
Chlorphendianol	Lysozyme HCl	Sulconazole nitrate (topical)
Chlorzoxazone	Meclofenamic acid	Sulfacetamide (topical)
Clemastine	Meclozine	Tetrahydrozoline
Clobetasol butyrate (topical)	Mepyramine maleate	Tolmetin
Croconazole	Mequitazine	Tolnaftate
Cromoglicic acid	Methenamine	Triclosan
Cyproheptadine	Methocarbamole	Tripelennamine
Decaline	Miconazole & hydrocortisone (topical)	Trip(r)olidine
Dexbrompheniramine	Naratriptan	
Dexchlorpheniramine	Natamycin (topical)	

Table 4: Active pharmaceutical ingredients which are not approved/not marketed in Austria

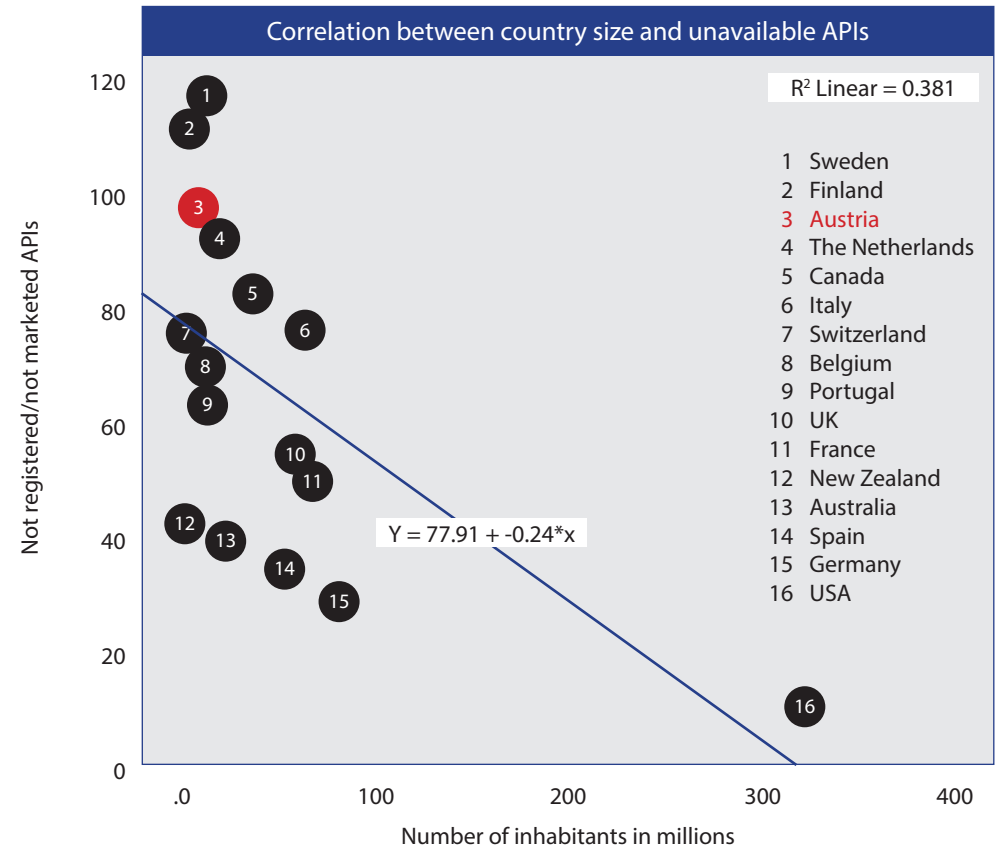


Figure 9: Correlation between country size and products that are not available

A limiting factor for the above-described considerations is the fact that the existing self-care sector – especially in Austria – also comprises a series of preparations with active substances that are not classified as medicinal products. Any assessment of the opportunities for self-care that is exclusively based on the availability of medicines will be distorted if it doesn't take in account such dietary supplements, balanced diets and medical devices.<sup>34</sup> This statement likewise applies to medicines for special therapies (phytotherapy, homeopathy and anthroposophy) which are traditionally of great importance for the self-care sector in Austria.

A further point of criticism is that the overview of prescription status given above tends to distort or overestimate the “OTC backlog” of countries like Austria, because many older substances are obsolete with a view to the current state of medicine. In this respect the specific substance gaps are not equivalent to supply gaps. Therefore, an additional evaluation is ne-

<sup>34</sup> Especially in the USA some of the substances are also available without prescription because they are not classified as medicines there.

cessary which examines how many innovative switches of selected reference countries have also been implemented in Austria. This question will be evaluated in Chapter 3.3.2.2.

## 3.2 Prioritisation Criteria for Switches

### 3.2.1 Risk Assessment and Consumer Protection

(in Cooperation with Dr. Christoph Baumgärtel, AGES, as Co-author)

Consumer protection is the highest-ranking maxim of every pharmaceutical regulatory evaluation of the safety of use of medicinal products and their classification in terms of the prescription status. In this respect, both a risk situation that is adequate for self-care and a positive risk to benefit ratio are necessary, but also sufficient conditions for the switch of a substance to the non-prescription status. This means that the risk assessment is the natural entrance criterion for the prioritisation of potential switches. Without existing safety concerns a restriction of patient autonomy and literacy, as regularly exerted by the prescription status, is not legitimised. As a consequence, a concerned substance is predestined for a switch, regardless of the subsequent prioritisation criteria. Where documented and empirically relevant safety concerns do exist, such concerns will be at least one important argument for downgrading them in terms of priority for a switch or even a complete exemption from a switch.<sup>35</sup>

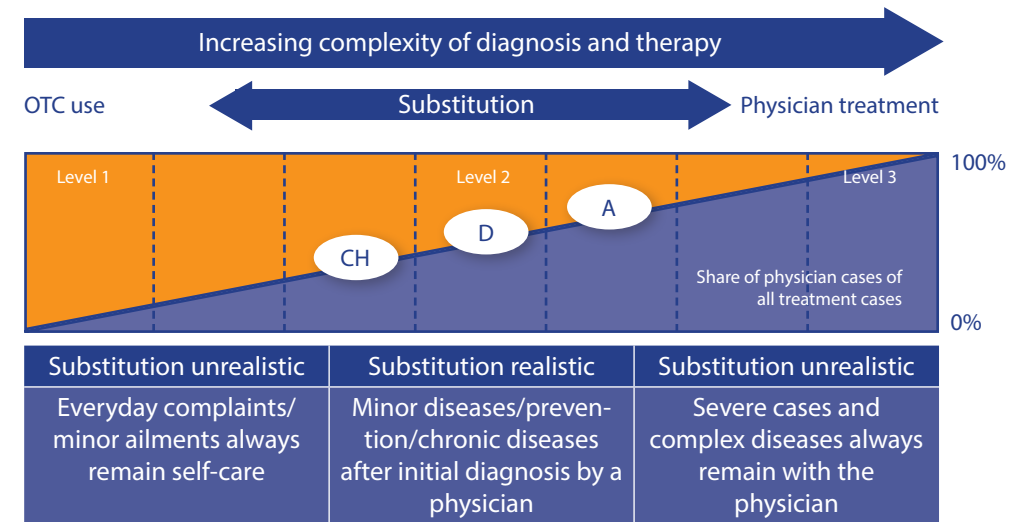
However, in practice the situation will be completely clear only in very few cases. In these cases, medical and pharmaceutical reservations that directly affect the suitability of a substance for self-care are to be balanced against direct or indirect effects which may also be safety-relevant or of any other interest. Of course, the risk assessment must always be based on the best available evidence.

It should be widely agreed upon that there are a large number of common and trivial opportunities for self-care that require neither a medicine nor professional help. At the same time, on the opposite edge of the spectrum of treatment opportunities, there is an area that undoubtedly requires a differential diagnosis and, where necessary, further medical assistance. In between, there is an area that provides a certain scope for substitution in the sense of intensified or optimised self-care. The following Figure illustrates this connection and demonstrates, with the example of the three German-speaking countries (A, CH, D), that the margins are exploited to varying degrees as a result of specific national frameworks for self-care.<sup>36</sup>

<sup>35</sup> Cf. EU-Kommission (2006): A Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use. Article 74a of Directive 2001/83/EC amended by Directive 2004/27/EC. Internet: [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide\\_160106\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide_160106_en.pdf) (Accessed: 16.11.2017).

<sup>36</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

These frameworks may be characterised by aspects which positively affect the depth of self-care (as in Switzerland), as well as a wide availability of over-the-counter substances (as in Germany). Particularly in the case that an extension of self-care by new substances becomes open for discussion, the possible risks of self-care explicitly move into focus.



CH: Switzerland, D: Germany, A: Austria

Figure 10: Substitution ranges between self-care and physician care

Based on the study of relevant literature in this area, three main theses that are sometimes used among experts as arguments against a positive risk-benefit ratio of self-medication can be identified. According to these theories, treatment of laypersons without medical supervision would entail the risk of protraction or chronification of a disease, addiction to medicines and incorrect use, or abuse of medicines, as well as promoting the risk of side effects and interactions.

Fundamentally, there should be a discussion of whether the specific risks and side effects of self-medication can in practice be avoided through medical treatment.<sup>37</sup> Self-medication medicines often comprise products for which a prescription version is also available. For both similar risks and spectrums of side effects can be assumed. This applies in particular to those cases where medicines are prescribed by physicians (OTx), which can likewise (identically) be used in self-care. The potential for specific risks from self-medication thus result from the behaviour of physician, pharmacist and patient. There needs to be clarification over whether the

<sup>37</sup> Major parts of the following information are based on the respective presentation given in May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.



handling of OTC products by these three players leads to a use- and risk-relevant difference between self-medication and treatment by a physician.

The legal conditions in Austria show clearly that uncontrolled self-medication is counteracted by legislation. The compulsory prescription and the strict criteria for switches have a restrictive impact on the market. In addition to the prescription requirement, the requirements for marketing authorisation and the post-authorisation surveillance, the “pharmacy-only principle” is a key factor for the promotion of patient safety. Besides the physician the pharmacist, with his expert advice, plays a vital role in preventing the improper application of OTC products.<sup>38</sup> Due to this function pharmacists enjoy a high reputation in the Austrian population. This has also been demonstrated by the GfK study conducted within this project, with 91% of the 1,000 respondents assessing pharmacy recommendations as credible. This value roughly equals the perceived credibility of physicians (94%). The importance of on-site pharmacies compared to online pharmacies is highlighted by the fact that nearly 75% of the customers buy their OTC medicines and health products on site and not following offers from the internet.<sup>39</sup>

For the risk-benefit evaluation of self-medication, and for assessing the suitability or necessity of a prescription with a view to the improvement of drug safety, the physician should be used as a reference criterion. In this respect, around 30 years ago the renowned health economist Prof. Peter Oberender had already stated: *„As the prescription requirement does not provide as much patient protection as is often claimed, it should be reduced to such medicines that represent a real danger for human health. The adjective “real” should be very sparingly applied in this regard (...).“*<sup>40</sup> In fact, since then it has been demonstrated in various studies that the professional sovereignty of the physician must not necessarily be a guarantee for avoiding medication risks, including the exclusion of side-effects or interactions. A general risk can therefore not be completely excluded with medical treatment either. Concerns relating to self-medication with regard to safety should therefore be adequately relativised. It seems unlikely in many cases that the existing risks and side effects of the medicines would be prevented through more restrictive legislative action, because these problems result from the use of medicines per se.

With regard to the assessment of the actual protective function of compulsory prescription status in real-life conditions, it cannot be ruled out that in medical practice a significant portion of prescription medicines de facto come to the consumer without a personal contact

<sup>38</sup> Cf. Winterstein, A., Jopp, R. und Schaefer, M.: Patienten profitieren von der Pharmazeutischen Betreuung. In: Pharm. Zeitung 146 (2001) 13, pp. 1024–1033.

<sup>39</sup> Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.

<sup>40</sup> Oberender, Peter (1984): Mehr Wettbewerb auf dem Arzneimittelmarkt: Eine ursachenadäquate Therapie. Wirtschaftsdienst, ISSN 0043-6275, Verlag Weltarchiv, Hamburg, Vol. 64, Iss. 9, pp. 455–461.

with the doctor, i.e. without a clinical assessment of the patient. This practice is particularly pronounced in the treatment of chronic diseases that is characterised by an initial medical diagnosis and subsequent prescriptions. According to the GfK survey, more than half of patients who have seen a doctor in the past three months (before the interview) have experienced, at least once, that a prescription was directly issued by the ordination assistant and without any physician contact, and 10% indicated that they experienced this practice three times or more within the three-month period.<sup>41</sup> The possible argument that the respective prescriptions are “only” repeat prescriptions, could in turn serve as a starting point for a discussion over whether at least partial OTC switches could perhaps be taken into consideration for numerous indications and substances after initial medical diagnosis. When assessing the instrument of the compulsory prescription, it must additionally be taken into account that one of the most frequent responses of patients in case of a health disorder is to take a medicine from their medicines cabinet and to use this medicine.<sup>42</sup> This comprises both non-prescription as well as previously prescribed and not or not completely consumed medicines, i.e. residual quantities of prescription medicines. A study, conducted on behalf of the European Commission, showed that this problem is particularly commonplace in Austria when compared with the total EU.<sup>43</sup> It is deemed logical to assume that the problem is not only restricted to antibiotics, but could also affect many Rx substances. This practice largely undermines the putative protective effect of restrictive provisions that are already in place in many locations today.

Although the legal conditions try to ensure the safety of an individual medicine as far as possible, the decisive criterion for a positive risk-benefit assessment of self-medication, in addition to the physician and the pharmacist, is the patient himself. It could be demonstrated that Austrian consumers handle OTC products responsibly and in no way imprudently. Also, the non-prescription status is by no means interpreted by the Austrian consumers as an expression of freedom of a preparation from risks or side effects.<sup>44</sup> Basic criteria such as the safety and efficacy of the product, as well as confidence in the product, are decisive factors for the choice of the patient. The generally hesitant attitude of Austrian consumers in the case of minor ailments reduces the risk potential of self-medication which could result from a “hasty” consumption of medicines. In particular, the decision between medical consultation and self-care is made carefully by the consumers, taking the state of personal information regarding the present disorder into account. According to the GfK survey, in the case of minor ailments

<sup>41</sup> Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.

<sup>42</sup> A representative examination in Germany has shown that the share of patients who make use of their medicine chest for self-care is 47%. The Nielsen Company (2015): Deutscher Gesundheits-monitor des BAH (Arztbesuche aufgrund leichter Gesundheitsstörungen).

<sup>43</sup> Cf. EU-Kommission (2017): Antimicrobial Resistance and causes of non-prudent use of antibiotics in human medicine in the EU. Internet: [https://ec.europa.eu/health/amr/sites/amr/files/amr\\_arna\\_report\\_20170717\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_arna_report_20170717_en.pdf) (Accessed: 16.11.2017).

Cf. DAZ online (2017d): Woher kommen Antibiotika ohne Rezept? Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/07/27/woher-kommen-antibiotika-ohne-rezept/chapter:all> (Accessed: 16.11.2017).

Cf. Salzburger Nachrichten (2017): Österreicher schlucken Antibiotika „vom Nachbarn“. Internet: <http://www.salzburg.com/nachrichten/gesundheit/sn/artikel/oesterreicher-schlucken-antibiotika-vom-nachbarn-258831/> (Accessed: 16.11.2017).

<sup>44</sup> Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.



more than two thirds of respondents rely on their own experience or get advice from their family and friends before consulting the internet or visiting a doctor's office or pharmacy. More than half of the patients had visited a pharmacy for the purpose of self-medication with non-prescription medicines. In almost a quarter of the cases the pharmacy was visited at the onset of first symptoms to get to advice or to buy an over-the-counter medicine.

Pharmacy, as an important interface between the patient and OTC medicines, promotes the safety of self-responsible use. It could be shown that – although not always actively offered – the options for advice and the individual utilisation by patients represent a key safety factor in the area of self-medication.

With this background, it can be summarised that both medical treatment and self-medication are subject to certain risks and side effects which are caused by the use of medicines in themselves. By this, it becomes clear that the specific risks of self-medication cannot be prevented by medical treatment alone. The benefit from the use of the medicines nevertheless outweighs the risk, regardless of the prescription requirement.

From an overall perspective, the previous results allow the conclusion that self-medication in Austria is safe and suitable for the treatment of minor ailments under the given conditions and that the risk-benefit balance is positive.

Despite the high safety standards in self-medication, there will always be a certain inevitable residual risk. Minimising this risk must be the subject of further design of the regulatory framework for the supply of medicines and health care. For this purpose the interfaces in the Austrian health care system should be more closely connected and the capacity of the consumer to make informed decisions and assume responsibility for his own health and health prevention be strengthened. Providing patient-oriented information and increasing pharmaceutical advice can further make an important contribution to risk minimisation. Last but not least the introduction of e-medication and ELGA (Note of the translator: electronic patient record) which have already entered the testing phase and shall be rolled out gradually in 2017<sup>45</sup> can also contribute positively in this respect. The combination of physician and pharmacist can increase the efficiency of self-medication and render the risk-benefit relationship more and more positive.

The foregoing discussion focused on the risk situation resulting directly from the use of medicines in self-medication or under medical supervision. For the regulatory decision for or against the OTC status of an active substance, several other aspects can also play a role that

<sup>45</sup> Cf. z. B.: Austria Presse Agentur (2017): Elga: Österreichweite E-Medikation soll im Frühjahr starten. Internet: <http://derstandard.at/2000051453487/Elga-Oesterreichweite-E-Medikation-soll-im-Fruhjahr-starten> (Accessed: 16.11.2017).

affect risks at the medical level, but in an indirect way. These indirect effects are the result of supply aspects which are examined in the following Chapter. They will be discussed in the overall assessment (Chapter 3.2.4) together with the direct risks and consumer protection questions having been discussed above.

### 3.2.2 Health Policy and Care Policy Associated Aspects

(in Cooperation with Dr. Christoph Baumgärtel, AGES, as Co-author)

In systems where the eligibility for reimbursement is regularly linked to the compulsory prescription<sup>46</sup>, switches may imply the danger that certain patient groups would be excessively financially burdened, and that the population as well as some political groups perceive a switch negatively as an erosion of solidarity or an expression of rationing.<sup>47</sup> These risks can be cushioned to a greater or lesser degree if the switch is connected with the maintenance of the possibility of prescription and reimbursement of OTC products for specific patient groups (e.g. children and seniors), or up to a certain financial scope (e.g. so-called statutory benefits<sup>48</sup>, self-medication budget). Decoupling of the prescription-only status from solidarity-based financing can also be designed in a way that reimbursement is not linked to a medical prescription. In this way, the efficiency and profitability potential of self-medication could be fully exploited. The practical feasibility and the benefits of such approaches are well documented in the framework of the so-called Minor Ailment Schemes<sup>49</sup> in the UK based on many years of experience and well proven by different pharmacoeconomic studies.

<sup>46</sup> This regulatory situation in which two extraneous perspectives and legal areas, i.e. the drug law which is oriented at consumer protection and social law dealing with questions of reimbursement, are linked to each other in an unjustified manner, has for examples been existing in Germany since 2004.

<sup>47</sup> Cf. Döring, I. / Puteanus, U. (2012): Almosen für die Selbstmedikation. Wenn das Geld für Arzneimittel fehlt. In: Deutsche Apotheker Zeitung Nr. 21, S. 86.

Cf. Döring, I. / Puteanus, U. (2013): Selbstmedikation bei sozial Benachteiligten und die Folgen bei Verzicht. Meeting Abstract. Gesellschaft für Arzneimittelanwendungsforschung und Arzneimitteltelepidemiologie e.V. (GAA). 20. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimitteltelepidemiologie. Düsseldorf, 05.-06.12.2013. Düsseldorf: German Medical Science GMS Publishing House; 2013.

Cf. Döring, I. / Puteanus, U. (2014): Selbstmedikation bei sozial Benachteiligten. Zwischen Verzicht und umstrittenen Arzneimitteln. Internet: [https://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKewi705yl2ePXAhXFL1AKHUIJCM4QF-ggoMAA&url=https%3A%2F%2Fwww.lzg.nrw.de%2F\\_media%2Fpdf%2Fpharma-zie%2Ffanwendungssicherheit%2Fposter\\_selbstmedikation\\_bei\\_sozial\\_benachteiligten.pdf&usq=AOvVaw2lncy\\_jrghQM1Sl6zTddVh](https://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKewi705yl2ePXAhXFL1AKHUIJCM4QF-ggoMAA&url=https%3A%2F%2Fwww.lzg.nrw.de%2F_media%2Fpdf%2Fpharma-zie%2Ffanwendungssicherheit%2Fposter_selbstmedikation_bei_sozial_benachteiligten.pdf&usq=AOvVaw2lncy_jrghQM1Sl6zTddVh) (Accessed: 29.11.2017). [https://www.lzg.nrw.de/\\_media/pdf/news/2014/poster\\_selbstmedikation\\_bei\\_sozial\\_benachteiligten.pdf](https://www.lzg.nrw.de/_media/pdf/news/2014/poster_selbstmedikation_bei_sozial_benachteiligten.pdf) (Accessed: 16.11.2017).

Cf. Puteanus, U. (2015): Selbstmedikation bei sozial Benachteiligten. Eine Befragung bei Tafelnutzerinnen und -nutzern. Vortrag bei einem Symposium des Landesentrums Gesundheit Nordrhein-Westfalen (LZG.NRW) am 29.09.2015 in Düsseldorf. Internet: [https://www.lzg.nrw.de/\\_media/pdf/service/Veranst/150929\\_dialog\\_versorgungsforschung/15-09-26-Selbstmed\\_sozial\\_Benachteiligte\\_Puteanus.pdf](https://www.lzg.nrw.de/_media/pdf/service/Veranst/150929_dialog_versorgungsforschung/15-09-26-Selbstmed_sozial_Benachteiligte_Puteanus.pdf) (Accessed: 29.11.2017).

<sup>48</sup> Statutory benefits can be offered by health insurance funds as additional voluntary benefits beyond the basic services. They include, for example, benefits in the areas "natural therapies" (e.g. homeopathy), "pregnancy and perinatal medicine" (e.g. artificial fertilisation) or "vaccinations" (e.g. for private travels).

<sup>49</sup> Minor Ailment Schemes are programmes of the National Health Service (NHS) for the promotion of self-care in pharmacies in England and Scotland. The approach combines elements of pharmaceutical care focused on minor ailments with financial incentives at patient and pharmacy level. Depending on the specific design, a MAS can cover the dispense of OTC medicines to pharmacy customers free of charge or the remuneration of pharmaceutical care (both financed by the NHS). The concept is further accompanied by pharmacy trainings and a public campaign for the education of consumers in self-care topics.

For example, an observational study with 377 participants by Watson et al. (2014) showed that the reduction of symptoms after visiting a pharmacy is higher (with an average of 44.3%) than after visiting an emergency institution (37.3%) or a physician (35.7%).<sup>50</sup> The most frequently given reason for selection of the treatment setting was the assumed appropriateness and patient comfort with a view to the existing symptoms. The average costs vary between GBP 29.30 in pharmacies and GBP 147.09 in emergency settings. As a result the health-related outcomes are on a similar level, but the costs in pharmacies are by far the lowest. Therefore, the authors of this study recommend shifting the demand for the treatment of minor ailments to the community pharmacy setting.<sup>51</sup>

In a systematic review focusing on pharmacy-based Minor Ailment Schemes (PMAS), Paudyal et al. (2012) found out that physician consultations due to minor health problems lead to costs amounting to GBP 2 billion every year in the UK. One of the included studies estimated that savings to the NHS would amount to GBP 112 million (in 2008/2009) if all physician consultations due to minor health problems were to be replaced by PMAS. The reason for this effect would primarily be due to lower average costs in pharmacies but with similar health outcomes. Other studies were also able to demonstrate a relief of the burden on general practitioners in terms of minor health problems as well as a lower volume of prescriptions.<sup>52</sup>

It can therefore be stated at this stage, as an important premise, that aspects of distribution and social policy can be systematically separated from both measures to create a self-care friendly market environment and from the switch issue.<sup>53</sup> This clearly means that the promotion of switches is not only compatible with a liberal ideology focusing strongly on personal responsibility, but also with a socio-political approach which dedicates the highest and unalienable priority to the idea of solidarity and social equality.

With a view to the regulatory situation in Austria, this premise is already accepted in the current situation: there are no general statutory criteria determining when a medicine has to be switched and at the same time it can be further listed in the green area of the EKO (Note of the translator: Austrian codex for the reimbursement of medicines), meaning that it will also be reimbursed. Each case is decided on an individual basis. However, the prerequisites for ongoing eligibility for reimbursement are that it is classified in the “green box” and that it has been used (under prescription) for a long time. As a result, Austrian patients can continue to get non-prescription medicines refunded after an OTC switch in conjunction with a physician consultation.

<sup>50</sup> It has to be taken into account that the severity of symptoms played a major role for the choice of the treatment setting.

<sup>51</sup> Cf. Watson, M. C. et al. (2014): A cohort study of influences, health outcomes and costs of patients' health-seeking behaviour for minor ailments from primary and emergency care settings. *BMJ Open* [Online] 5(2). Im Internet verfügbar unter: <http://bmjopen.bmj.com/content/5/2/e006261.full> (Accessed: 16.11.2017).

<sup>52</sup> Cf. Paudyal, V., Watson, M. C., Sach, T. et al. (2013): Are pharmacy-based minor ailment schemes a substitute for other service providers? In: *British Journal of General Practice*, 63 (612): S. e472–e481.

<sup>53</sup> Cf. z. B. May, U., Bauer, C. (2017): Apothekengestützte Selbstbehandlung bei leichteren Gesundheitsstörungen – Nutzen und Potentiale aus gesundheitsökonomischer Sicht. In: *Gesundh ökon Qual manag* 2017; 22: S. 12–S. 22.

However, a key factor for the prioritisation of potential switch candidates is the evaluation of the specific effects on the care situation that may be connected with the OTC switch of a substance. It has already been mentioned in the context of the risk assessment criteria that the legal prescription status of medicines has, in many cases, a direct influence on the behavior of consumers towards their health disorders. Low-threshold access to an OTC medicine might determine whether a health disorder is treated with medicines or treated at all. This similarly applies to the preventive use of medicinal products, for example vaccines. This fundamental question of curative or preventive treatment in contrast to “therapeutic nihilism” is highly relevant from a care perspective. Without treatment there will be no positive effects on the health-related quality of life of patients, which could otherwise be expected from treatment. Moreover, no treatment or prevention may have further negative effects in the form of an aggravation or chronification of a health disorder. This relationship constitutes an important inter-face between the treatment rate and the risk assessment of potential switches. However, with a view to indirect costs and economic perspectives, both care-related effects associated with switches (i.e. the effects on the quality of life) and the subsequent risks of no treatment, are relevant. In the first case, this relates to work and productivity losses that are directly due to the health impact of the disease, while in the second case, new complications or disorders resulting from no treatment or failure of prevention (low vaccination rate) are to be attributed. In particular, the declining vaccination rates for many preventive vaccines (e.g. influenza), which have been falling in Austria for years despite efforts of health policy, give rise to alternative strategies to improve this situation sustainably through a low-threshold access to care in the future. The following figure (Figure 11) summarises the numerous effects which can result from the access to care.

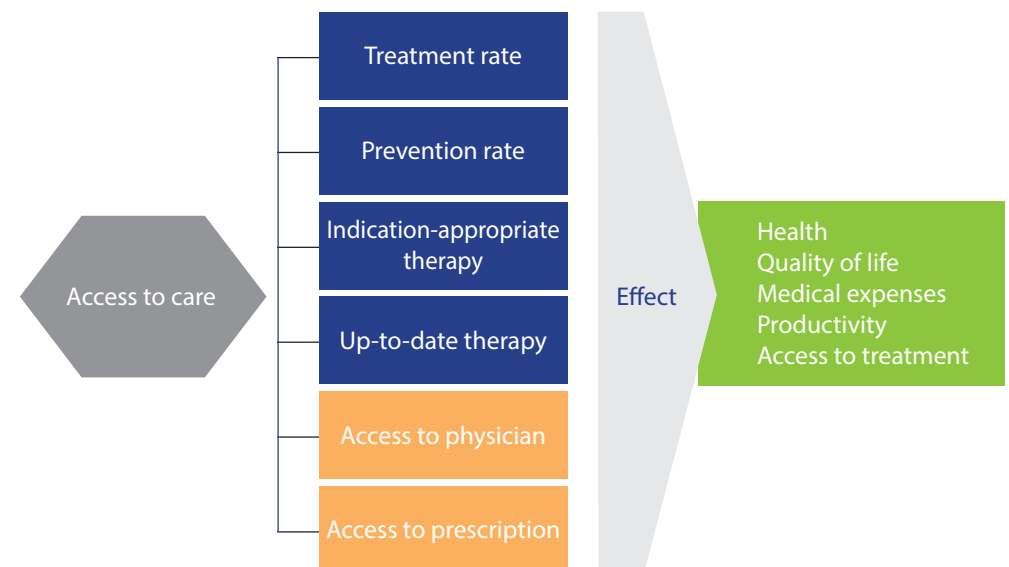


Figure 11: Multiple effects of the access to care

### 3.2.3 Market Relevance and Economic Potentials

Firstly, pragmatic considerations speak in favour of a prioritisation criterion for switches that takes the market relevance of a prescription substance and expected economic potential after the switch into account. Further considerations relate to health economic arguments. The market relevance, as measured by the sales of the substance under prescription or the projected sales of the respective OTC products, is directly connected with the interests of the market players on both the supply and the demand side in the respective switch. These interests promote the practical feasibility of the project and justify increased efforts, both on the supply side under economic aspects and on the side of authorities under aspects of regulatory economy. In addition, market relevance is a criterion which can be much more simply objectified and quantified than, for example, the results of the risk-benefit evaluation.

From a health economic perspective, besides the importance of sales which are particularly reflected in the possible cost-saving effects, the volume component is also important. From this, conclusions can be derived on the relevance of a substance for care, as well as potential effects on direct costs outside of the pharmaceutical sector (e.g. physician costs) and indirect costs i.e. costs for the national economy, as well as benefit-related effects and effects on the quality of life. In terms of an overall evaluation (see the following Chapter 3.2.4), the health economic effects resulting from the market relevance can even be indirectly incorporated in the risk-benefit assessment which constitutes a priority criterion for the evaluation of switches.

### 3.2.4 Overall Approach for the Prioritisation and Evaluation of Switches

For the overall evaluation of the issues discussed above, an advanced approach to the definition of the medical risks associated with switches and self-medication arises from the perspective of the authors.

The classical approach to risk evaluation is essentially restricted to substance-related risks and application-related risks of potential OTC medicines. In the following Figure 12 these risks are called direct medical risks. For demarcation and as an extension to these risks, care- and scarcity-related risks are summarised as indirect medical risks. The latter risk categories are related to social and care policy aspects that were characterised in Chapter 3.2.2.

Care-related risks means all risks resulting from the availability or non-availability of over-the-counter medicines and, by this, certain treatment options. In certain circumstances, a low-threshold access to care can be a basic prerequisite for diseases to be adequately treated

or prevention to be exercised. From this, (indirect) medical risks may likewise emerge that should be ranked equally to direct medical risks. The same applies to (so-called) scarcity-related risks arising from limited availability, e.g. in the out-patient medical care setting. In indications for which adequate options for self-care are not available, the system of outpatient/primary care is typically used. This results in prolonged waiting times for a physician appointment, longer waiting times in the physician office and shorter times for treatment by the physician per patient.<sup>54</sup> Consequently, this raises the hurdle for the use of medical assistance in such cases where it would necessarily be indicated. This, but also the shortened time for treating the patient and delays until the use of treatment, impairs the quality of care with subsequent medical risks.<sup>55</sup> Both the direct and the indirect risks immediately lead to economic risks. Such economic risks relate to costs incurred in outpatient or inpatient care as a result of over-, under- or inappropriate supply of care. This includes the treatment of adverse drug reactions as well as e.g. the disease costs that are directly related to low vaccination rates.

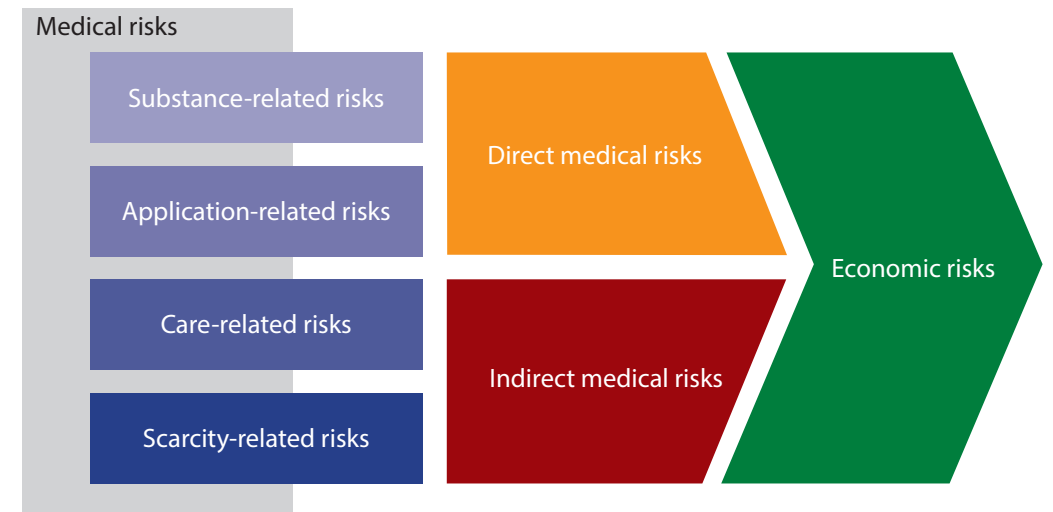


Figure 12: Direct and indirect medical risks

<sup>54</sup> The time aspects described here were quantified in: May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

<sup>55</sup> In terms of the scarcity-related risks, as they are defined here, the discussion and assessment of the medical risks and limitations of switches and self-care have to consider that the danger of incorrect diagnosis or failure of diagnosis and, by this, delay of diseases can not only provoke increased self-care, but that this danger is further increased if physicians are forced to make diagnoses of important cases under high pressure due to work overload. According to an evaluation of 90 studies by the Institute of Patient Safety at the University of Bonn up to 680,000 severe medical errors occur in Germany every year. Around 17,500 patients die of the consequences of such errors. According to a European survey 72% of the Germans assessed medical errors as an important problem. Every third individual (29%) personally fears such errors. Cf. Hoffmann, B., Rohe, J. (2010): Patient Safety and Error Management – What Causes Adverse Events and How Can They Be Prevented? Dtsch Arztebl Int 2010; 107(6): 92–9. Lack of time is one of the most frequently given reasons when it comes to errors of diagnosis, where the incidence is relatively high. Cf. Albers, R., Gottschling, C., Mayer, K. M., Meiners, M., Reinhard, J. (2013): Altraum Fehldiagnose. In: FOCUS Magazin Nr. 8 (2013). Internet: [http://www.focus.de/digital/multimedia/titel-altraum-fehldiagnose\\_aid\\_921147.html](http://www.focus.de/digital/multimedia/titel-altraum-fehldiagnose_aid_921147.html). (Accessed: 16.11.2017). The lack of time is particularly pronounced in the offices of general practitioners during the peak flu season and by this in connection with consultation occasions in which more self-care would clearly be imaginable.

The above-described concept of expanded medical risks with the categories of indirect and direct medical risks has far-reaching implications in terms of the question how the assessment of an OTC switch of a substance can be addressed systematically.

The classical view, as it is currently established in many European countries, sets the starting point of the evaluation on the question of whether a specific substance is used in self-care or in physician treatment. In both cases, the evaluation focuses on possible risks arising from, for example, undesired effects or incorrect use of the medicinal product. Furthermore, the risk of delay or masking of an illness is considered for both treatment paths. Whether the risks of use of a specific substance in self-care outweigh the risks of use under medical supervision are definitive in the official decision on prescription status. If they do, a decision against the switch would have to be taken. The following Figure (Figure 13) illustrates this view. An approach which extends this classical approach, without however abandoning the basic elements, is the so-called Brass model.<sup>56</sup> Following this approach the assessment of potential switches should also include possible benefit-related effects. These include, among others, an improved access to supply and savings for the health care system.



\* The extension of the comparison by **benefit-related aspects** conforms to the proposal of Professor Eric Brass (UCLA, USA) et al. (co-called Brass model).

Figure 13: Classical approach for the risk-benefit assessment of switches

Neither the classical approach being currently practiced nor the approach further developed in the Brass model are completely suitable for decision-making on the prescription status of individual active substances under real-life conditions: Authorities can take decisions on the prescription and dispense status of a medicine, but not about how they are used in everyday life by the patients.

The starting point of the idea presented here is the patient who, faced with a particular treatment choice, is confronted with the situation that a specific substance is either available with-

<sup>56</sup> Cf. Brass, E. P., Lofstedt, R., Renn O. (2011): Improving the decision-making process for nonprescription drugs: a framework for benefit-risk assessment. In: Clin Pharmacol Ther. 2011 Dec. 90(6): 791–803. doi: 10.1038/clpt.2011.231. Epub 2011 Nov 2.

out prescription or not. Within the meaning of a decision-theoretical approach, both situations result in different behavioural options which he will consider with a view to his personal benefits (Figure 14).<sup>57</sup>

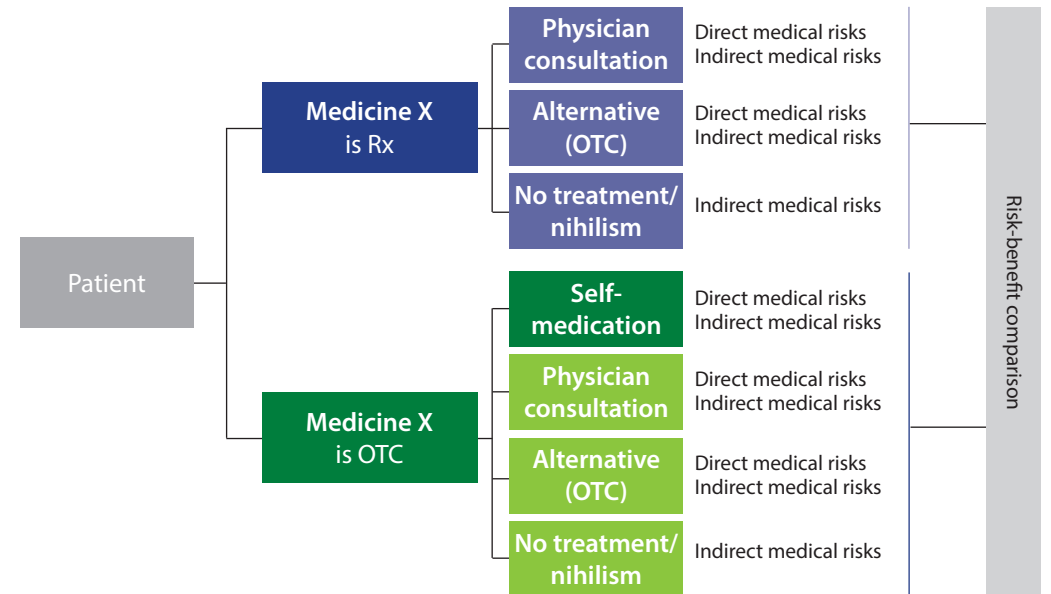


Figure 14: Approach for the risk-benefit assessment according to May and Bauer

If the respective medicinal product is under prescription, the option of self-medication with the specific substance will not be available. Firstly, this means that the patient can go to a doctor to get a prescription for it. Secondly, he can alternatively choose a non-prescription substance or thirdly, he can remain with no treatment. If the medicine has an OTC status, he can also go to a doctor, but there is the new option of self-care with the substance. Furthermore, he can likewise choose an alternative over-the-counter substance or not treat himself (no treatment/nihilism).

For the assessment, in real-life conditions, of whether the prescription status is advantageous or disadvantageous compared to the OTC status from the consumer perspective, a multi-dimensional risk comparison involving all practical therapy paths must be performed. In this scenario the prescription status of a substance would be justified if the associated risks are lower than with OTC status for the substance. Within this assessment the four categories of direct and indirect risks defined in Figure 12, including in particular supply risks, will play a key role, and will in many cases lead to another decision than the one resulting from the classical

<sup>57</sup> For this, factors such as the time needed as well as the eligibility for reimbursement will also play a role.

approach.<sup>58</sup> This approach is of special importance for the assessment of the so-called innovative switches which will be discussed in Chapter 3.3.2. In this particular area, the classical approach falls short because these substances or their therapeutic indications regularly exceed the traditional scope of self-medication, leading to special care-related effects.

### 3.3 List of Proposals for Switch Candidates

The following concrete proposals for substances which are to be switched in Austria, are entirely based on the above-described assessment criteria. However, the list is divided into two sections based on two fundamentally different approaches. The first approach comprises the status quo resulting from the regulatory history and the substance and indication gaps in Austria as having been identified in Chapter 3.1 after an international comparison. The described prioritisation criteria are operationalised with the aid of a scoring model, resulting in a distinct ranking in the sense of an ABC analysis.

The second approach, which is used afterwards, refers to visionary, i.e. clearly ambitious switch projects. For these, it is also discussed on the basis of the defined criteria in detail which switches are predestined for an OTC switch in Austria, independent from the question of existing substance gaps in the international comparison.

#### 3.3.1 Switches on the Basis of Substance Gaps

##### 3.3.1.1 Selection Procedure and Ranking List of Top Switch Candidates

In Chapter 3.1 so-called substance gaps in the Austrian OTC market were identified with the aid of an international comparison of fifteen countries. Now, proposals for OTC switches shall be derived on the basis of these substance gaps. Priorities for these proposals will be set with the aid of the criteria described in Chapter 3.2. A three-stage scoring model was developed for operationalisation of these criteria with a view to a priority list.

<sup>58</sup> This approach implies that switches and the limitations of self-care are also discussed in the light of findings concerning the quality of diagnosis of the respective disease in the general physician practice. This quality has often been shown to be suboptimal, especially in the treatment of complaints such as headache or migraine which in principle are also accessible to self-care with non-prescription medicines. Striking deficits have been documented in this area, both in terms of diagnosis and therapy. Cf. DAK (2007): DAK Gesundheitsreport 2007, Schwerpunktthema: Kopfschmerz und Migräne. Hamburg 2007. S. 38–95.

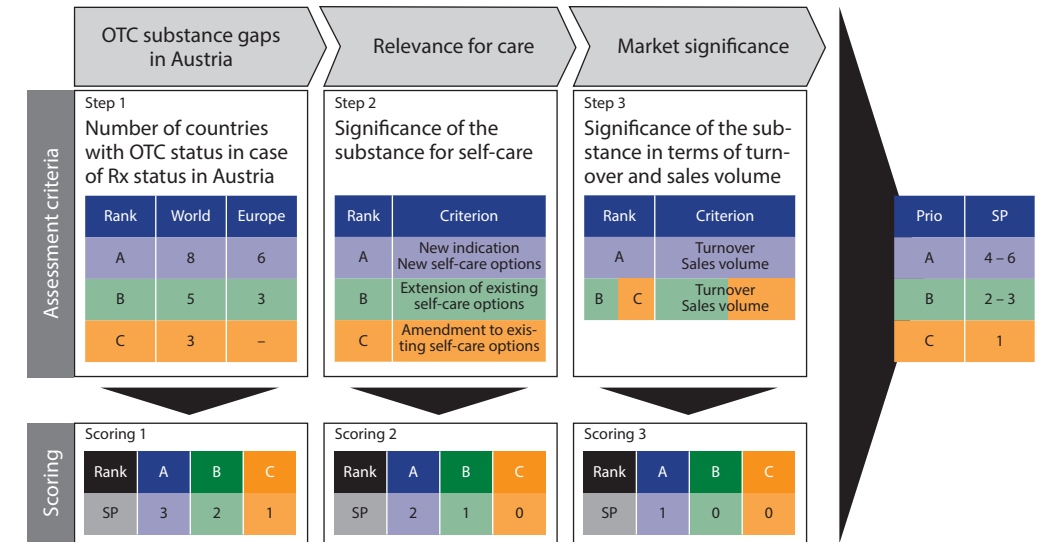


Figure 15: Three-stage scoring model

Prio: Priority class, SP: Scoring points

At the first stage, the importance of the detected substance gaps is determined by the number of selected comparison countries in which the concerned substance is available without prescription. Wide international availability indicates on the one hand that numerous licensing and market surveillance authorities have classified the OTC status as justifiable under risk aspects. Furthermore, the number of countries in which a substance was switched indicates the importance for care that is assigned to the substance within the framework of self-medication. The substance gaps are classified in three classes according to an ABC analysis. The highest class A to which three scoring points (SP) are awarded is reserved for substances that are available without prescription in the majority of countries of the world-wide selection and at the same time in the majority of European countries. For further classifications see Figure 15.

The assessment of the relevance for care at the second stage is likewise performed according to an ABC analysis, focusing on the significance of the substance for self-care. As can be seen in Figure 15, switches that open up a new indication or a completely new option for self-care achieve the highest priority. For further classifications see also Figure 15.

The third stage deals with the market significance on the basis of data from the institutes QuintilesIMS and Insight Health as a further prioritisation criterion.<sup>59</sup> A high rating in terms of turn-over and/or sales volume indicates a potentially high level of interest from market players and thus high chances of a successful switch (Figure 15). In addition, high importance

<sup>59</sup> Cf. Heilhecker, J. (2017): Marktpotentiale von Rx-to-OTC-Switches in Österreich. Eine gesundheitsökonomische Analyse auf Basis eines Mehrländervergleiches. Bachelorarbeit, Hochschule Fresenius, Idstein. (Zur Publikation eingereicht)



in terms of sales volume is an indicator for the relevant significance of the substance for care. The weighting of the three described criteria between each other is performed in decreasing order, with the number of countries above the relevance for care, and then down to the market significance. As can be seen in the schematic illustration of the scoring model, a three-stage categorisation according to an ABC analysis can also be made on the basis of the awarded scoring points (SP) for the overall result.

The following table (Table 5) contains the ranking list of top switch candidates as derived with the aid of the procedures from the scoring-model shown in Figure 15, including their respective main indications.

Rank	Active pharmaceutical ingredient (API)	Main therapeutic indication
1	Diclofenac (oral)	Minor to moderate acute and chronic pain
2	Mometasone (nasal)	Hayfever and all-season sniff (corticosteroide-related)
	Ketoprofene	Severe to very severe acute and chronic pain
3	Cimetidine	Stomach and duodenal ulcers
	Cinchocaine (topical)	Haemorrhoids and ruptures at the anus and rectum
	Codeine	Cough suppressant
	Desloratadine	Allergic reactions (antihistaminic agent)
	Doxylamine succinate	Minor problems with falling asleep
	Hydrocortisone (topical)	Minor to moderate allergic, itching or inflammatory skin diseases
	Meclozine*	Nausea, vomiting, vertigo
	Metoclopramide	Nausea, vomiting
	Noscapine (Noscapine + Guaifenesin)	Cough suppressant
	Sucralfate	Stomach and duodenal ulcers
	Sumatriptan	Migraine

Table 5: Top switch candidates in Austria

\* This API is currently not registered in Austria.

The relevance of this list is derived from the fact that it results from an approach to evaluating the existing substance gaps for non-prescription medicines in Austria according to the criteria discussed in this study. The list represents a basis for discussion. It explicitly does not claim to overrule normative assessments, particularly if such assessments are made under the auspices of consumer protection and risk assessment in the specific framework of the Austrian health care market. With this constraint, the list can serve as a basis for further reflection

and discussions with medical and pharmaceutical professionals, especially with the Austrian experts, who are entrusted with regulatory issues and the safety of medicines use.

Some summary aspects as well as aspects that are applicable across substances with regard to the risk-benefit assessment of switch candidates, in addition to their potentials in terms of turnover and sales volumes, are presented in the two following Chapters.

### 3.3.1.2 Risk-Benefit Discussion of the Switch List

(in Cooperation with Dr. Christoph Baumgärtel as Co-author)

The above list of switch candidates is not based on an explicit risk-benefit analysis, but implicitly on official switch decisions in other countries, i.e. the international prescription status. With this background, an additional assessment of the list of switch candidates shall be provided from a specifically Austrian perspective. The list, which was created on the basis of the operationalisation of the prioritisation criteria, represents only a basis for further considerations.

With a view to risk evaluation from the national Austrian perspective, but also relevant European safety assessments, it must be further subjected to closer examination by authorities and stakeholders involved in the respective decisions. In particular, substance-specific risk evaluations must and should be included in the further use of this list. Recent pharmacovigilance findings might especially reduce the suitability of individual substances for switches that have at first glance been highly prioritised by the list, which reflects among other facts the marketing authorisation and market realities of the past few years. At the same time, substances with a slightly lower priority could prove better switch candidates after consideration of all of the circumstances that are to be taken into account. The evaluation and realisation of the switch potentials shall thus be the subject of an outstanding, intense discussion with experts from the health care system, industry and authorities. Based on consensus in such discussions and a legally correct implementation, OTC switches of one or another active substance on the basis of the candidate list may present a welcome initiative and efficient measure to strengthen the capacity of the Austrian population for self-care.

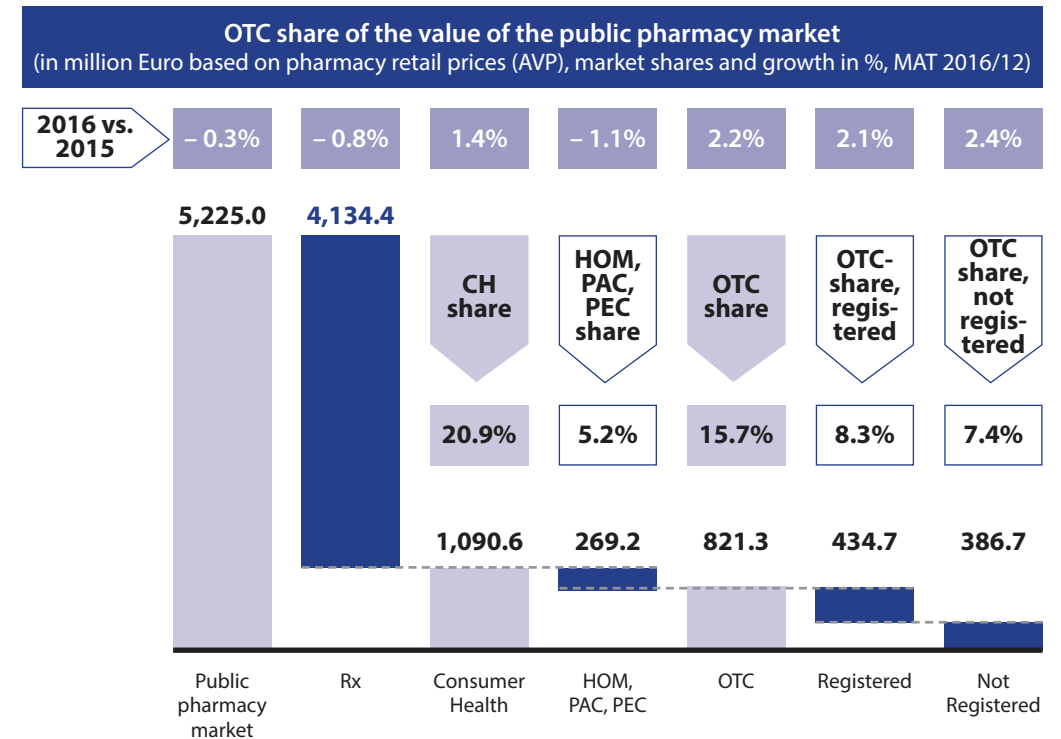
### 3.3.1.3 Sales and Sales Volume Potentials of the Switch List

The turnover volumes of the top switch candidates included in Table 5 can be measured on the basis of market data from the institutes QuintilesIMS and Insight Health, with the exclusion of the active ingredient meclizine which is currently not registered in Austria. The re-



maining 13 active substances recommended for a switch total a turnover of EUR 32,301,997. This value corresponds to the sales which these substances that are currently under prescription have achieved in Austria in 2016. The three substances with the highest priority for a switch recommendation, i.e. diclofenac (oral), mometasone (nasal) and ketoprofene have alone achieved a combined turnover of EUR 20,199,616 in their current Rx status. This value is also based on the turnover achieved in Austria in 2016.

The turnover of the OTC market pharmacy market in Austria for the year 2016 is estimated as EUR 821.3 million (at pharmacy retail prices, AVP). The market of registered OTC products relevant for the switch topic accounts for a share of EUR 434.7 million of this value.<sup>60</sup> This corresponds to per capita expenditure in the registered OTC market of EUR 49.90.<sup>61</sup> Putting the total volume of switches that are recommended in this report in relation to the current total turnover of all registered OTC medicines, this would result in an additional turnover equivalent to a share of 7.43% of the existing market. The three prioritised recommendations alone would already equal 4.65% of the existing market of registered OTC medicines, diclofenac (oral) clearly accounting for the largest share (3.74%). Considering the whole OTC segment, the OTC share (in value) of the total public pharmacy market would then rise from 15.7% to 16.23%.



CH: consumer health | HOM: homeopathy | PAC: patient care | PEC: personal care

Figure 16: OTC share of the value of the public pharmacy market<sup>62</sup>

The expected sales volumes can also be estimated on the basis of the existing data. The total sales volume of the top switch candidates in 2016 amounted to 4,177,150 packages, of which 2,306,282 go to the top three candidates. Overall, about 73 million units of registered and non-registered OTC products (Note of the translator: i.e. dietetic food, food supplements, cosmetics, medical devices etc.) were dispensed in community pharmacies in Austria in 2016. The implementation of the switch proposals would mean an increase of dispensed OTC products by 5.72%. The top three candidates alone would account for an increase of 3.16%.

These figures demonstrate the economic potential of the switch recommendations. In addition, conclusions can be made as to which costs to payers could be saved through switches, provided they prove successful in the sense that they positively influence the self-medication market in Austria in terms of its depth and breadth. Furthermore, it can be expected that in some cases the market importance of concerned indications and substances as a whole will increase through the switch, so the provided figures tend to underestimate the actually realisable volume of the switches.

<sup>60</sup> Cf. Quintiles IMS Daten cited after: IGEPHA (2017c): Jahresbericht 2016. S. 10 und 11.

<sup>61</sup> Calculated on the basis of 8.712 million inhabitants in Austria.

<sup>62</sup> Quintiles IMS, cited after: IGEPHA (2017c): Jahresbericht 2016. Wien 2017.

### 3.3.2 Visionary Switch Projects

Put against the background of the identified substance gaps and the rather restrictive switch climate in Austria, switches which are internationally considered as innovative or even represent so-called “first-in-world switches” are currently of a more visionary character for the Austrian market. This however, in no way curtails the motivation to discuss them scientifically here and to make serious proposals in this regard.

#### 3.3.2.1 Demarcation and Specifics of Innovative Switches

The common characteristic of innovative switch proposals lies merely in the fact that they go beyond the traditional limits of autonomous self-care. As can be seen in the “axis cross chart” created by the AESGP (Figure 17), they may relate to indications that can be diagnosed by an individual and are of short-term nature, but not conform to established standards of an adequate risk-benefit ratio (e.g. emergency contraception). The majority of the innovative switch candidates are, however, characterised by the fact that neither of these criteria, self-diagnosis and/or short-term or temporary health disorder, considered as prerequisites for sufficient suitability for self-medication, are fulfilled. Therefore, a relatively simple and standardised categorisation and distinction between prescription and OTC status cannot be made. So the first step of identification of such switch candidates requires an evaluation on a case-by-case basis which meets the heterogeneity and complexity of such cases.

Despite this fact, the applicability of the basic criteria for the evaluation and prioritisation of switches, as derived above, is not questioned. They include consumer protection, risk evaluation, relevance for care and potential market significance, factors determining whether a switch is medically justified and interesting from the perspective of (health) economy. Besides these factors, in the case of innovative switches there are often very specific effects relating to the overall assessment of the risk-benefit situation. One particular effect that can be argued in favour of a switch is the influence on the (extended) access to supply of the medicine. It can be assumed that there is an undersupply in various indication areas because of the hurdles patients face when trying to see a doctor, in particular due to time constraints. An approach that handles this comprehensive point of view was described in Chapter 3.2.4 as an overall evaluation for the prioritisation of switches. Besides substance-related risks and application-related risks, it also includes the care-related risks and scarcity-related risks defined in this expertise.

The fact that the majority of innovative switches, seen in isolation, are associated with higher application-related risks than many established OTC substances, is not the expression of a

modified weighting of the risk aspect or an increased readiness to assume risks. It is moreover the expression of an advanced risk perspective, which not only considers the direct risks of the application of the medicine, but also indirect risks that can come along with the Rx status of a substance in a real-world setting. These risks relate on the one hand to the medical consequences that occur when substances are not administered under Rx status despite being required medically. On the other hand, certain indirect medical risks are to be taken into account that may be reduced by switches. They are related to freeing up the resources of the health care system and the beneficial use of them. In addition to the risk assessment, the two outlined constellations also relate to the benefits angle, i.e. effects on the quality of life of patients as well as health-economic and economic aspects that are regularly associated with such switches.

Many innovative switches can create a new situation where entire indication areas or partial indications are available for self-care for the first time. Corresponding examples from switch history are the switches of nicotine for smoking cessation, creating the precondition for the success of medical smoking cessation and the high health-economic importance of this opportunity, as well as the switch of levonorgestrel and ulipristal for emergency contraception.<sup>63</sup>

Some experts see a concrete approach to broadening the basis for self-care, which exceeds the outlined switch options in the classical sense, by opening up certain chronic diseases to self-care by patients after an initial diagnosis by a physician. In this regard, the Association of the European Self-Medication Industry (AESGP) has developed a proposal that is potentially very far-reaching when compared with the current areas of self-medication in European countries and especially in Austria (see Figure 17).

<sup>63</sup> Cf. May, U., Bauer, C., Grande, F. (2013): Erstattungsfähigkeit der Nikotinersatztherapie im Rahmen der GKV, in: MVF 01/2013, 6. Jahrgang, 05.02.2013. S. 40–43.  
Cf. Wasem, J., Jung, M., May, U. et al. (2008): Nutzen und Kosteneffektivität der Nikotinersatztherapie zur Raucherentwöhnung – eine entscheidungsanalytische Modellierung der direkten medizinischen Kosten, in: Gesundheitsökonomie & Qualitätsmanagement, 13. Jahrg., Nr. 2, April 2008. S. 99–108.

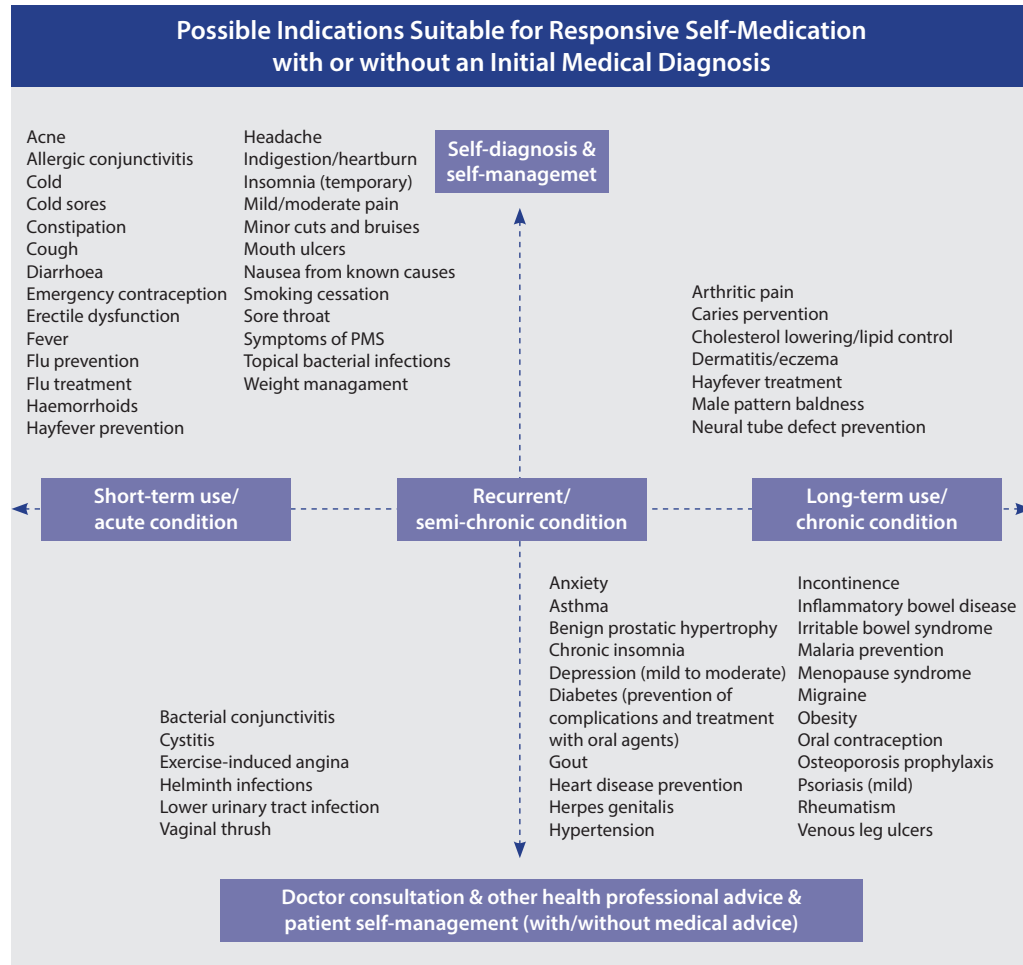


Figure 17: AESGP Discussion proposal for potential indications for self-care<sup>64</sup>

According to this proposal, the indications are divided into four quadrants, corresponding to their suitability for self-diagnosis and their short- or long-term duration. The established areas of classical self-responsible self-medication can be found in the upper quadrant on the left side. They are characterised by short-term, usually self-limiting conditions that can be diagnosed and managed by the concerned persons themselves. The right upper quadrant extends this range with indications that are not necessarily temporary, but chronic. The conditions in the left lower quadrant are also short-term, temporary conditions, but for which the capability of self-diagnosis is not necessary. In accordance with the proposals in the right lower quadrant, even medically diagnosed chronic conditions needing continuous monitoring could be an area of enhanced personal responsibility and self-medication based on switches.

<sup>64</sup> AESGP

These proposals therefore lie completely outside the classical focus of self-medication on minor health disorders and, by this, only partially comply with the definition of self-care, which typically also includes self-diagnosis.<sup>65</sup>

### 3.3.2.2 International Comparison of Innovative Switch Activities

On the basis of the developed database, this Chapter analyses to what extent innovative switches were made in Austria in recent years. For the first step, all first-in-world switches which have been carried out in the past 15 years in one of the 16 countries surveyed were recorded. There were eleven in total. In a second step, it was determined how many of these switches were concretely implemented in the countries or implemented as a follow-up switch in the same year. The result of this evaluation is shown in Figure 18. Countries with a high first-in-world-switch activity have a larger share of green fields in the charts. On the basis of this analysis, four reference countries were selected whose switch activities can be considered as innovative. The criterion for selecting these countries was a comparatively high number of first-in-world switches during the past 15 years.<sup>66</sup> In this way, Australia, Germany, the United Kingdom and New Zealand were identified as reference countries. As shown in Figure 18, the number of implemented first-in-world switches is relatively large in these countries compared to the other countries under consideration.<sup>67</sup>

<sup>65</sup> Cf. May, U., Bauer, C. (2017): Apothekengestützte Selbstbehandlung bei leichteren Gesundheitsstörungen – Nutzen und Potentiale aus gesundheitsökonomischer Sicht. In: *Gesundh ökon Qual manag* 2017; 22: S12–S22.

<sup>66</sup> The USA was on the same level as New Zealand, but not chosen as a reference country due to the fragmented data basis.

<sup>67</sup> Excluding switches that were implemented across Europe via a harmonised switch, as they were not based on individual decisions of countries and can therefore only partially be classified as innovative.

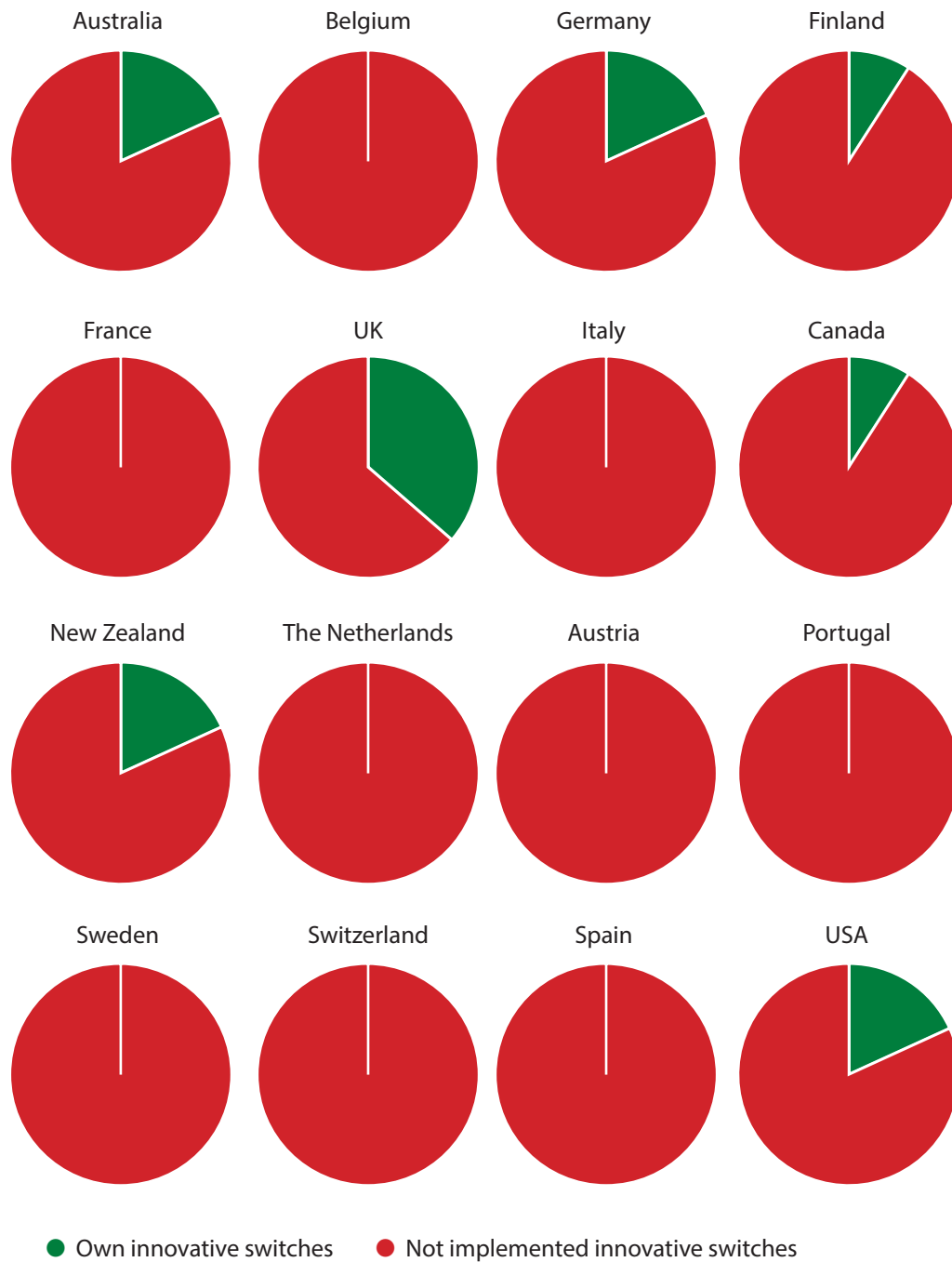


Figure 18: First-in-world switches

The following figure (Figure 19) was developed on the basis of the identified reference countries. It shows how the switch behavior of the 16 examined countries must be classified with regard to its innovative character in relation to the reference countries. Substances that have so far not been switched in any of the reference countries were excluded from the evaluation, because their innovativeness has to be assessed as relatively low. The dark green fields in the chart symbolise switches that were made either before or at the same time as a reference country or, in the case of the reference countries, the switches that were made there. Central European switches are also included here. Light green fields symbolise switches which were made after the switch in at least one reference country. The red colour stands for prescription medicines which were switched in at least one country (and in the case of a reference country in at least one further country). Substances that are not marketed in a respective country, or where there is no information, are symbolised in grey. This procedure results in the following picture for the comparison across the countries in terms of innovative switch activities.



Figure 19: Innovative switches on the basis of the reference countries

The above investigation reveals that there is a backlog of demand in Austria, particularly with a view to innovative switches. Austria neither excels in the area of follow-up switches of substances nor in switches of substances that have been switched before or together with a reference country. Moreover, the size of the fields is to be put into perspective even considering the included pan-European switches. The share of active substances which are not available, either through existing prescription status or because they are not marketed, is also high in the international comparison. The large grey field in the graph of the United States can in particular be explained by missing information for many substances.

It can therefore be concluded that Austria's previously detected backlog, in terms of the number of medicines which are internationally available without prescription, cannot be ascribed only to gaps in the area of old substances, but also to the area of innovative switches.

### 3.3.2.3 Innovative Switch Candidates for Austria

The proposals for innovative switch candidates in Austria, provided for discussion below, are based on newer switch literature, on suggestions by the innovative projects of switch pioneers such as the authorities in New Zealand and the United Kingdom, as well as on the previously cited expert survey carried out by the authors.<sup>68</sup> A further starting point is the "axis cross chart" developed by the AESGP in cooperation with external experts (see Figure 17). This chart, in addition to the traditional domains of self-medication, also comprises conditions which are of long-term or chronic nature and would only be eligible for self-care after initial medical diagnosis.

The discussion and classification of possible innovative switch candidates is again performed with the aid of the assessment criteria defined in Chapter 3.2 of this expertise, i.e. in particular on the basis of the presented advanced approach for switch assessment (Figure 14). Formal operationalisation with the aid of the scoring model for the weighting of risk, supply and market aspects (Figure 15) is waived here because the switches under consideration are of such individual character that a standardised or uniform assessment is not deemed appropriate. With this background, the following proposals were determined (Figure 20). The respective details will be explained below:

<sup>68</sup> Cf. May, U., Bauer, C. (2017): Apothekengestützte Selbstbehandlung bei leichteren Gesundheitsstörungen – Nutzen und Potenziale aus gesundheitsökonomischer Sicht. In: *Gesundh ökon Qual manag* 2017; 22: S12–S22. The experts included in the survey on the topic "self-medication" also comprised representatives from the departments for drug safety and the expert committees for prescription in Austria and Germany.

Vaccinations	<ul style="list-style-type: none"> <li>Rx-to-OTC switch of different vaccines for the prevention of e.g. influenza, FSME</li> <li>Vaccination immediately in the pharmacy</li> </ul>	Elevation of vaccination rates
Erectile Dysfunction	<ul style="list-style-type: none"> <li>Rx-to-OTC switch of e.g. sildenafil and other APIs</li> <li>Extended requirement for advice in pharmacies</li> </ul>	Risk of falsified products in case of internet purchases
Asthma	<ul style="list-style-type: none"> <li><i>On-demand medication</i>: short-acting beta-2-mimetics after initial medical diagnosis</li> <li><i>Long-term medication</i>: repeated prescription of inhaled corticoids/pharmaceutical care</li> </ul>	Elevation of treatment rates
Eye Infections	<ul style="list-style-type: none"> <li>Rx-to-OTC switch of topical antibiotics (e.g. gentamicin, kanamycin)</li> <li>Extended requirement for advice in pharmacies</li> </ul>	Fast access to care
Migraine	<ul style="list-style-type: none"> <li>Rx-to-OTC switch of all triptans</li> <li>OTC with restrictions on package sizes</li> </ul>	Avoidance of underuse and misuse of healthcare

Figure 20: Discussion proposals for innovative switches in Austria

API: active pharmaceutical ingredient

A far-reaching proposal, which means not only a change of prescription status of various active ingredients, but also an extension of the competences of the pharmacist, concerns the dispense of certain vaccines without prescription. These switches only gain practical importance for the process of care if the vaccine can directly be applied in the pharmacy, without consultation of a physician. The discussion covers in particular routine and booster vaccinations in adults for which the risk-benefit ratio for specific target groups has been carried out by the National Panel of Immunisation and which are included in the Austrian Vaccination Plan (such as influenza, encephalitis, measles). Eventual risks that could occur during the immunisation process, caused due to the absence of a physician, are to be balanced in this case against the benefits of an increased immunisation rate and the resulting reduced sickness and infection risks. Austria, as other European countries, generally complains about low vaccination rates.<sup>69</sup> Italy has recently implemented mandatory vaccination by law<sup>70</sup>, while France has extended its existing strict obligation of vaccination by eight additional vaccines.<sup>71</sup> Inter-

<sup>69</sup> Cf. Ministerium für Frauen und Gesundheit (o.J.): Masern. Internet: (Accessed: 16.11.2017).

<sup>70</sup> Cf. Feldwisch-Drentrup, H. (2017): Italien führt unter Protesten Impfpflicht ein. In: DAZ Online. Internet: [https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/05/22/italien-fuehrt-unter-protesten-impfpflicht-ein?utm\\_campaign=kurzNach6&utm\\_source=20170522&utm\\_medium=newsletter&utm\\_keyword=article](https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/05/22/italien-fuehrt-unter-protesten-impfpflicht-ein?utm_campaign=kurzNach6&utm_source=20170522&utm_medium=newsletter&utm_keyword=article) (Accessed: 16.11.2017).

<sup>71</sup> So far, diphtheria, tetanus and polio were mandatory in France. Now whooping cough, hepatitis B, Haemophilus influenzae type b, pneumococci, meningococci, measles, mumps and rubella are added as mandatory vaccinations with significant threat of punishment in case of non-compliance. Cf.: Feldwisch-Drentrup, H.: Frankreich weitet Impfpflicht deutlich aus. Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/07/10/frankreich-weitet-impfpflicht-deutlich-aus> (Accessed: 16.11.2017).

national experiences demonstrate that vaccination rates can also be significantly increased without such compulsory measures by a low-threshold access in the proposed form, and that the resulting potential benefits exceed the risks.<sup>72</sup> In Switzerland, vaccination by pharmacists has accordingly been gradually expanded across the majority of the cantons after successful testing stages in the first cantons.<sup>73</sup>

One proposal, which is currently being tested in the UK in model projects and has already been implemented in Poland, is the switch of **sildenafil for erectile dysfunction**. There is no doubt that the active ingredient should be used with restraint or at best under medical supervision, particularly in patients with certain pre-existing conditions or risk factors. Regardless of the usefulness of a physician consultation, it should be discussed to what extent prescription status would actually ensure medical control under “real-life conditions”. This must be done with a view to the fact that many consumers bypass seeing a doctor, often using dubious online offers from abroad. The products delivered in this way are subject to high risk of counterfeiting, making them inactive, which would be less harmful, or in the worst (not rare) case, dangerous for the users.<sup>74</sup> The possible rationale for the relevant Rx-to-OTC switch lies just in these application-related risks arising from the indication-specific high risk of falsification. The psychological barrier for consumers with erectile dysfunction to visit a pharmacy is – also in this context – considered to be lower than the psychological and also temporal barrier of a physician consultation. In order to address the risks of use, the dispense in pharmacies could be connected with particular due diligence measures, in particular with a standardised query concerning the existence of personal risk factors of the consumer. If the patient turns out to possess risks in terms of the medicine from this safety check, referral from the pharmacy to a physician would be obligatory.

The specific feature of the application of **anti-asthmatics** relates to the chronic nature of the disease. The need for medical anamnesis and diagnosis of asthma in connection with the adjustment of medication should not be a point of discussion here. In the further course of the disease asthma patients typically learn to manage it and in particular to assess when and how to treat acute episodes. The long-term use of medication becomes routine and rapid and immediate availability of the medicinal product in case of an emergency a necessity. There does not seem to be any benefit resulting from compulsory consultation with a physician to get a repeat prescription. At the least, not every required package of long-term medication (typically an inhaled corticosteroid) would require a doctor visit. Hence, this is a prime example of the reasonable utilisation of repeat prescriptions. Taking the non-prescription status

<sup>72</sup> Cf. Gauld, N. (2017): Switch and pharmacist-supply: a view from abroad. Vortrag im Rahmen der ersten Switch-Konferenz des BAH am 06.07.2017.

<sup>73</sup> Cf. Apotheke adhoc (2017): Zug: Apotheker dürfen zur Spritze greifen. Internet: <http://www.apotheke-adhoc.de/nachrichten/internationales/nachricht-detail-internationales/schweiz-zug-apotheker-duerfen-zur-spritze-greifen/?L=&chash=d11d6237e6ef-422f07979753e730f7da> (Accessed: 16.11.2017).

<sup>74</sup> Cf. OTC bulletin (2017): Pfizer UK wants to switch sildenafil. In: OTC bulletin Nr. 480 v. 07.04.2017. Solihull 2017. S. 1.



of anti-asthmatics for rescue medication (e.g. with the short-acting beta-2-mimetic salbutamol) into consideration would also imply a waiver for a repeat prescription, provided self-care is based on an initial medical diagnosis. Subsequent supply and education of patients concerning, for example, the handling of anti-asthmatics, which includes the use of inhalation aids and the peak-flow meter, as well as a mandatory annual lung function test, could be covered by a special pharmaceutical care programme for asthmatics. At regular intervals (approximately every six to eight weeks), a comprehensive review interview of the patient by the pharmacist would be useful. A recent study from Italy shows the benefit of pharmacies in asthma treatment and thus provides argumentation to allow respective treatment options for patients via self-care.<sup>75</sup> A model project in Hamburg has also underpinned the great benefits of pharmaceutical care for asthma patients.<sup>76</sup>

In the case of **antibiotic substances for use in bacterial eye infections**, easy and rapid availability is often beneficial for those affected because the complaints are very unpleasant and inconvenient. At the same time, they can be easily recognised by medical lay persons and often even immediately be associated to an apparent infection. A further argument in favour of self-care is the immediate onset of action. To make self-care even safer, non-prescription dispensing could be linked to extended requirements for advice in pharmacies. That the medicines contain an antibiotic substance should not be a preclusion for the Rx-to-OTC switch, as they are applied topically and resistance would develop much less frequently due to the high and effective concentration of the active ingredient at the infection site.<sup>77</sup>

**Triptans for use in migraine** represent a highly effective treatment for a disorder which clearly exceeds the range of minor ailments. Migraine-related symptoms cause significant limitations for affected persons in everyday and working life. Migraine is associated with high direct and indirect i.e. economic costs.<sup>78</sup> Whereas the direct costs cover expenditures for interventions (physician consultations, medicines prescriptions), indirect costs relate to the sick-leave days and reductions in productivity through impaired performance of the patients.<sup>79</sup> It shall be emphasised that the affected patients are typically younger and middle

<sup>75</sup> Cf. Blasius, H. (2017): Studie aus Italien: Asthmatherapie besser und kosteneffektiver dank Apotheker. In: DAZ Online. Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/05/18/asthmatherapie-besser-und-kosteneffektiver-dank-apotheker> (Accessed: 16.11.2017).

<sup>76</sup> Cf. Schulz, M. (1998): Der Asthmapatient. Wissenschaftliche Vortrags- und Fortbildungsveranstaltung der Apothekerkammer Westfalen-Lippe, Münster. 25. April 1998. Cited after: <https://www.deutsche-apotheker-zeitung.de/daz-az/1998/daz-21-1998/uid-3371> (Accessed: 16.11.2017).

<sup>77</sup> In contrast to systemic use of antibiotics in which only a limited part of the administered medicines can in fact exert an antibacterial effect at the target site, the concentration of the active substance is more efficient in case of topical administration.

<sup>78</sup> Cf. z. B. Linde, M., Gustavsson, A., Stovner, L. J. et al. (2012): The cost of headache disorders in Europe: the Eurolight project. In: *Eur J Neurol*, 19(5). S. 703–711.

Cf. z. B. Wilp, R. (2011): Medikamentenkosten, Arbeitsausfall, Mehrfacherkrankungen: Sozioökonomische Folgen von Kopfschmerzen. Internet: <https://idw-online.de/de/news429835> (Accessed: 16.11.2017).

<sup>79</sup> Cf. z. B. Göbel, H., Braun, J., Petersen-Braun, M., Gessner, U. (2016): Pharmakoökonomischer Nutzen der Selbstmedikation in Deutschland – Empirische Untersuchung am Beispiel von Migräne und Kopfschmerzen. In: *Gesundheitsökonomie und Qualitätsmanagement* 2016; 21(01): S. 23–29.

aged and are thus often active in working life or have important social responsibilities in their families. It is therefore of great significance from the perspective of health economy and national economy that the affected persons get an adequate and best possible treatment for their migraine attacks.<sup>80</sup> With this background, the Austrian Society for Pain (ÖKSG) and the German Society for Migraine and Headache (DMKG) confirm the effectiveness and suitability of triptans (naratriptan) for self-medication.<sup>81</sup> In real-life conditions, the compulsory prescription for substances from the group of triptans often prevents this option. The sudden and violent occurrence of complaints, resembling a „knock-out“, precludes a (personal) physician consultation in such an emergency. The same applies if the migraine attack occurs outside the consultation hours. In theory, affected patients could build up stocks of the prescribed medicines for the longer term, but such an idea is contradictory to the everyday experience of life and the human nature of forgetting and repression after the symptoms have subsided. De facto, with this background, a high degree of under- and incorrect supply in the treatment of migraine has been documented.<sup>82</sup> A more effective approach would be an exemption of all triptans from prescription, as the selection of the individually best acting triptan is to be determined in the interplay between patient and pharmacy, after initial medical diagnosis, using the “trial and error” principle. If this process is accompanied by repeated physician contacts, this can slow down the optimisation process or even completely impede it, so that under- or incorrect supply may continue. With regard to the protective function of the prescription requirement, which would be abandoned in this case, Göbel et al. state that the most common so-called excess-use headache in the treatment of migraine and headache is caused by certain classes of prescribed analgesics. They conclude that reducing self-medication in this indication area could lead to further incorrect and overuse, as well as follow-up costs.<sup>83</sup> Moreover, an incorrect use of triptans after an OTC switch is prevented by the fact that these substances typically exhibit a noticeable effect only in migraine (and not in tension headache). In this respect, there is no incentive for an application that is not indicated. The onset of the effect rather confirms the diagnosis.<sup>84</sup>

<sup>80</sup> Cf. Wöber, C. (2017): Praxis der Migränebehandlung. In: *Österreichische Ärztezeitung* 10, 25. Mai 2017. Internet: [http://www.aerztezeitung.at/fileadmin/PDF/2017\\_Verlinkungen/State\\_Migraenebehandlung.pdf](http://www.aerztezeitung.at/fileadmin/PDF/2017_Verlinkungen/State_Migraenebehandlung.pdf) (Accessed: 16.11.2017)

<sup>81</sup> Cf. Haag, G., Diener, H.-C., May, A. et al. (2009): Selbstmedikation bei Migräne und Kopfschmerzen von Spannungstyp. In: *Nervenheilkunde* 6/2009. Schattauer Verlag 2009. Internet: <http://www.dmkkg.de/files/dmkkg.de/patienten/Download/migraene%20und%20spannungskopfschmerz.pdf> (Accessed: 16.11.2017).

<sup>82</sup> Cf. z. B. Kailuweit, I. (2009): Kopf hoch – die innovative Therapie gegen Migräne. Vortrag zum 11. Berliner Dialog am 12.11.2009. Internet: <http://docplayer.org/15244482-Kopf-hoch-die-innovative-therapie-gegen-migraene-ingo-kailuweit-vorstandsvorsitzender-der-kkh-allianz-11-berliner-dialog-12.html> (S. 9, Accessed: 16.11.2017) und Wöber, C. (2017): Praxis der Migränebehandlung. In: *Österreichische Ärztezeitung* 10, 25. Mai 2017. Internet: [http://www.aerztezeitung.at/fileadmin/PDF/2017\\_Verlinkungen/State\\_Migraenebehandlung.pdf](http://www.aerztezeitung.at/fileadmin/PDF/2017_Verlinkungen/State_Migraenebehandlung.pdf) (Accessed: 16.11.2017).

Cf. z. B. Verband forschender Arzneimittelhersteller (VfA) (2007): Gutachten über die Unterversorgung mit Arzneimitteln in Deutschland. Internet: <https://www.vfa.de/download/gutachten-unterversorgung-am-d.pdf> (S. 38 ff., Accessed: 16.11.2017))

<sup>83</sup> Cf.: Göbel, H., Braun, J., Petersen-Braun, M., Gessner, U. (2016): Pharmakoökonomischer Nutzen der Selbstmedikation in Deutschland – Empirische Untersuchung am Beispiel von Migräne und Kopfschmerzen. In: *Gesundheitsökonomie und Qualitätsmanagement* 2016; 21(01): S. 23–29, und Saper, J. R., Da Silva, A. N. (2013): Medication overuse headache: history, features, prevention and management strategies. *CNS Drugs* 2013; 27: pp. 867–877.

<sup>84</sup> Cf. *Pharmazeutische Zeitung online* (2011): Beratungsentensive Blitzaableiter. Ausgabe 15/2011. Internet: <https://www.pharmazeutische-zeitung.de/index.php?id=37493> (Accessed: 16.11.2017).

Besides the above-described discussion proposals included in Figure 20, experts have proposed divergent innovative switches or indication areas for consideration for future self-medication.<sup>85</sup> They include antibiotics for use in recurrent uncomplicated urinary tract infections, statins for the self-management of cholesterol or acne medicines.<sup>86</sup> Taking the prioritisation criteria described in this expertise into account, the authors currently deem these proposals less suitable for Austria than the proposals included in Figure 20, which are commented on here in more detail.

It must be claimed for all innovative switch candidates under discussion that the risk-benefit assessment and decision making is carried out on the basis of an open and evidence-based analysis. Unfounded reservations are just as out of place here as arguments motivated by unilateral interests.

The size of sales volumes that could be shifted to the OTC market through the mentioned examples of innovative switches by far exceed those that could be achieved with typical switches from the area of the Austrian OTC substance gaps. Conversely, the savings arising for health insurance funds and the health care system are also significant. Due to the special aspects of innovative switches related to care, completely new consumer groups and indication areas would be opened up in many cases. As a result, OTC growth is not accompanied by cannibalisation of the Rx sales alone, the total sales of the switched products can moreover *ceteris paribus* be increased.<sup>87</sup>

<sup>85</sup> Cf. Gauld, N. (2017): Switch and pharmacist-supply: a view from abroad. Vortrag im Rahmen der ersten Switch-Konferenz des BAH am 06.07.2017.

Cf. Wilkes, D. (2015 c): New Ideas Better Ways. Making commercial sense of switching. In: OTC-Toolbox Innovations, Edition 5. Internet: <https://www.otctoolbox.com/innovations/making-commercial-sense-of-switching.aspx> (Zugriff am 29.11.2017). (Zugriff am 17.08.2017).

Cf. Kroth, E. (2017a): Switch – Wie steht Deutschland im internationalen Vergleich da? In: Gesundheitsökonomie & Qualitätsmanagement, 51/2017, 22. Jhrg., Thieme Verlag, S. 3–5, 11.

Cf. Cranz, H. (1985): Situationsanalyse, Beurteilung, Determinanten und Entwicklungstendenzen der Selbstmedikation. Kiel 1985. Cf. Abb. 17. AESGP-Diskussionsvorschlag zu potenziellen Indikationen zur Selbstbehandlung

<sup>86</sup> Cf. Ergebnisse der Experteninterviews in May, U., Bauer, C. (2016): Selbstbehandlung und Apotheke. Gutachten im Auftrag des BAH. Bonn 2016.

<sup>87</sup> The *ceteris paribus* clause relates to the fact that, depending on the indication, prices may develop very differently after the switch. Cf. hierzu Kapitel 3.3.1.3.

## 4 Implementation and Market Success of Switches

The discussion and deriving of criteria for the prioritisation of potential switches, as well as the identification of concrete switch candidates, are essentially only a purely academic exercise as long as there is no defined framework and no factors that have been identified that bring the implemented switches to practical market success. Likewise, the relevance for health economy and health policy will depend on this market success. With this background, it is essential at this point to consider the regulatory and procedural conditions, and subsequently the framework of the pharmaceutical market and the health system, as prerequisites for the market success of switches. In the latter context, the building blocks of a positive switch climate must also be described as starting points for a pro-switch policy in Austria and the special role of pharmacies.

### 4.1 Regulatory and Processual Framework Conditions for Non-prescription Status and Switches

Compulsory prescription can be assessed as relatively strict in Austria, as it partly also covers medicines that only lead to a few side effects when they are used properly and for the approved designated purpose.<sup>88</sup>

The key criteria for the decision of the Commission for Compulsory Prescription with regard to a possible switch are the data available for the concerned active substance and the extent to which patient safety is ensured. The Commission for Compulsory Prescription is an advisory body of the Ministry of Health. It discusses questions of the classification of substances, the deletion of no longer used active substances from prescription regulation, and changes of classification on the basis of scientific knowledge. In addition, it discusses proposals for amending prescription regulation.

The following Figure (Figure 21) shows that as a result of the regulatory framework, significantly more prescription medicines were approved in Austria than non-prescription medicines in the years included in the evaluation. In 2014 75% of the approved medicines were under prescription. A comparison of the years 2000 and 2014 demonstrates a reduction by about 450 approvals for prescription medicines, compared to a decline of about 2,200 approvals in the OTC sector. In contrast to this, in Germany for example, a total of 100,498 medicines were available in 2016, of which 52,614 were non-prescription and 47,884 were prescription

<sup>88</sup> Negative formulation in § 2 para 2 of the Prescription Requirement Act: '[...] that it (i.e. the finished medicinal product) is not subject to a restriction of dispense in the sense of a prescription requirement [...] it cannot present a danger to human or animal life or health when used within its designated purpose.'

medicines.<sup>89</sup> It is clear from these numbers that unlike in Austria the share of non-prescription medicines is larger than the share of prescription medicines. As there may be differences in the absolute count of products, the relative ratio of prescription and non-prescription medicines should further be taken into account for the comparison. The figures reveal that the percentage of non-prescription medicines on the pharmaceutical market in Germany is 52.35% and prescription medicines account for 47.65%. This means that the relative proportion of non-prescription medicines in Germany is also significantly greater than in Austria.

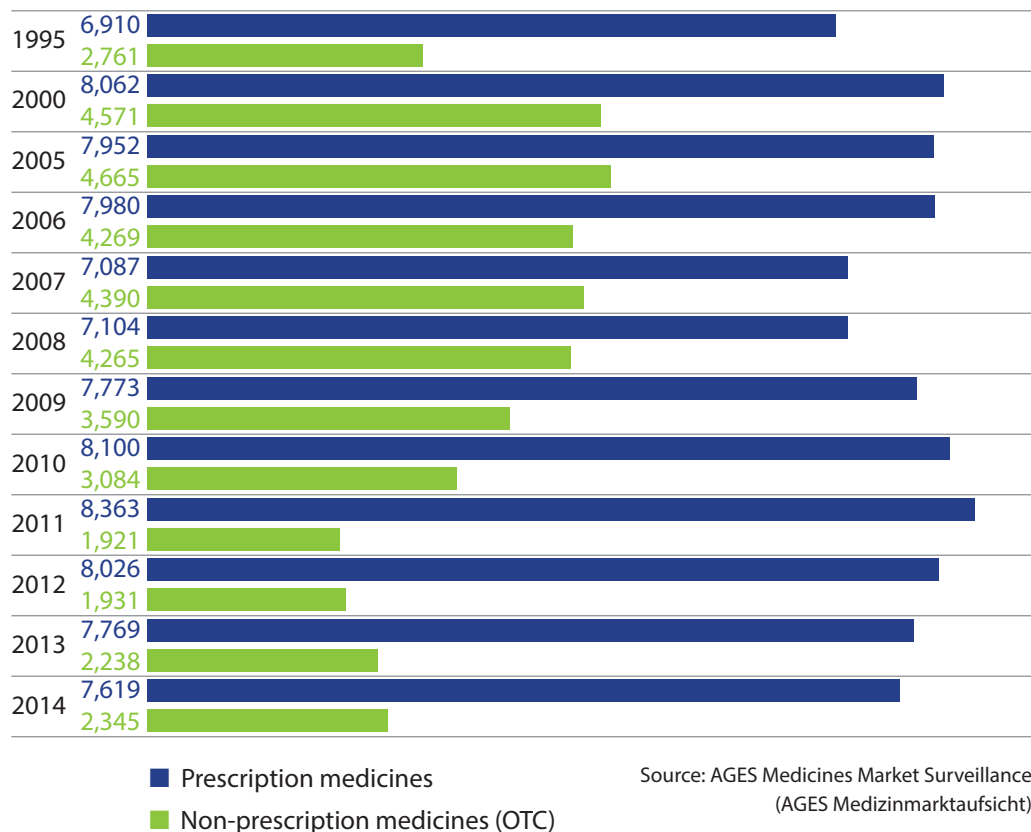


Figure 21: Prescription status of marketing authorisations 1995–2014<sup>90</sup>

<sup>89</sup> Cf. Bundesvereinigung Deutscher Apothekerverbände (ABDA) (2016b): Die Apotheke. Zahlen Daten Fakten 2016. Berlin 2016. S. 23.

<sup>90</sup> Pharmig (2016): Arzneimittel und Gesundheitswesen in Österreich. Daten & Fakten kompakt 2016. Internet: [http://www.pharmig.at/uploads/Daten\\_und\\_Fakten\\_2016\\_deutsch\\_web\\_15621\\_DE.pdf](http://www.pharmig.at/uploads/Daten_und_Fakten_2016_deutsch_web_15621_DE.pdf) (Accessed: 16.11.2017).

In Austria, there are two ways for the change of classification: the switch of an active substance and the switch of a medicinal product.

#### a) Switch of an active substance

If an active substance shall be switched, the first step is for the Commission on Compulsory Prescription, as advisory body of the Federal Ministry of Health, to discuss the change of classification. This usually happens at the request of a pharmaceutical company via the Chamber of Commerce. The next step is for the Commission to issue a recommendation to the Ministry. In practice this recommendation is implemented 1:1 as an amendment to the Compulsory Prescription Regulation. By this, the respective non-prescription substance is available for use in self-medication, either generally or under the specified conditions.

Six months later, pursuant to § 2 para 1 of the Compulsory Prescription Act, all medicines with the same active substance that meet the conditions set out in the Compulsory Prescription Regulation become OTC medicines. As a unique exception to this procedure, the Federal Office for Safety in Health Care (BASG) may later impose a restriction on the dispense of certain products by an administrative act.

#### b) Switch of a medicinal product

The second possibility for an OTC switch is the change of classification of a particular product. This requires an application for a variation to the marketing authorisation pursuant to § 24 para 2 of the Medicines Act at the Federal Office for Safety in Health Care. If this application is based on significant clinical or non-clinical data and these data were relevant for the assessment, the product is granted a data exclusivity period of one year for the respective data, pursuant to § 1 para 3a of the Compulsory Prescription Act. This means that no other product can be switched on the basis of the submitted data within one year.<sup>91</sup>

### 4.1.1 Formal Criteria for Rx-to-OTC Switches

As described above, there are two ways for classification to be changed in Austria, the switch of an active substance and the switch of a product. The following criteria, which are used for decision-making, are adapted to the so-called “switch guideline” of the EU Commission, which is of central importance for the safety evaluation of medicines in self-medication.<sup>92</sup>

<sup>91</sup> Cf. May, U. / Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013. S. 33 f.

<sup>92</sup> Cf. EU-Kommission (2006): A Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use. Artikel 74a of Directive 2001/83/EC amended by Directive 2004/27/EC. Internet: [https://ec.europa.eu/health/sites/health/files/files/eudrallex/vol-2/c/switchguide\\_160106\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudrallex/vol-2/c/switchguide_160106_en.pdf) (Accessed: 16.11.2017).

### Direct/indirect risks

Direct risks include substance-related dangers in terms of toxicity, interactions and side effects. Indirect risks means, for example, that the use of a medicinal product in self-medication might mask/hide an underlying condition that needs medical supervision. Indirect risks also includes the risk of the development of resistance through the use of medicines. With regard to these risks that would preclude the use of medicines without medical supervision, it has to be proven that the respective medicine has a low level of toxicity and that it is largely safe, both in terms of side effects and interactions with other medicines. In addition, masking of a serious disease through the uncontrolled use of the medicine must be excluded, in order to prevent a delay or failure of adequate treatment.

For the Commission, it is also of central importance whether the patient can assess the condition which shall be treated by self-medication by himself and treat it properly without medical supervision. This includes, among other things, knowledge of the natural course of the disease and its reoccurrence, as well as possible consequences due to this. These aspects have a direct impact on the product information, which shall assist the patient using a medicine in self-medication as much as possible.

### Incorrect use/misuse

Medicinal products shall be excluded from OTC status if they are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health. If the release of a medicine from compulsory prescription is requested, it must be thoroughly substantiated that such incorrect use is unlikely to occur.

### Recent authorisation/limited experience

Medicinal products containing substances for which there is still insufficient knowledge about their effects and side effects are not available for self-medication. This can, for example, apply to substances that have only been marketed for a short time or in the case of limited experiences with regard to their use because of low sales. Under these circumstances, exemption from the prescription requirement is usually only granted after several years of marketing. Of key importance for an OTC switch application is extensive post marketing surveillance data that reveals the use of the medicinal product in the population and substantiates the safety in self-medication beyond the scope of clinical data.

### Parenteral use

Due to additional risks, and the complexity of administration, parenteral medicines are generally deemed unsuitable for self-medication.

### Data requirements

In order for an application for exemption from the prescription requirement to be successful, so that the relevant product can be transferred to self-medication, all criteria mentioned in the switch guideline are to be addressed in the application and relevant data have to be submitted. An expert report should provide an overview of the existing clinical and non-clinical data, including a critical analysis of the use of the product in self-medication, and a justification based on the available data of why none of the criteria that determine the prescription-only status apply to the medicinal product. In compliance with the European switch guideline, the IGEPHA Switch Guide explains which clinical and non-clinical safety data should be listed.<sup>93</sup> This includes information about the clinical efficacy in cases where the indication, dosage or strength shall be changed.

Special focus within the evaluation of an application for the change of classification lies with the product information of the medicinal product, which must take the use in self-medication into particular consideration. Comprehensibility and readability possess the same great importance as precise information on the use of the product, such as recommendations for administration, contra-indications or warnings. Furthermore, where necessary, it must be stated when a doctor should be consulted.

The criteria of the EU Commission expressed in the switch guideline make clear that for a switch from Rx to OTC the risk-benefit ratio of the product or an active substance is always re-assessed with a view to the special situation of self-medication. This ensures a high degree of safety for the direct use of medicines by patients. This is also true for the evaluations performed by the Austrian Commission for Compulsory Prescription<sup>94</sup>, which advises the Ministry relating to the restrictions of the dispense of medicines as an advisory body.<sup>95</sup>

## 4.1.2 Procedural Aspects

Similar to the data exclusivity (data protection) that is applied in parallel to the patent protection for original products and is standardised across the EU<sup>96</sup>, a data exclusivity period of one year may be granted in the case of switch applications. The decision to grant this period, is taken in Austria by the Federal Office for Safety in Health Care (BASG), based on EU rules. Article 74a of Directive 2001/83/EC, amended by Directive 2004/27/EC, specifies:

<sup>93</sup> Cf. IGEPHA (2012): Switch-Guide. Wien 2008.

<sup>94</sup> Cf. BMFG (n. d.): Rezeptpflichtkommission. Internet: [https://www.bmgf.gv.at/home/Gesundheit/Medizin/Arzneimittel/Beiraete\\_und\\_Kommissionen/Rezeptpflichtkommission](https://www.bmgf.gv.at/home/Gesundheit/Medizin/Arzneimittel/Beiraete_und_Kommissionen/Rezeptpflichtkommission) (Accessed: 16.11.2017).

<sup>95</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013. S. 150 ff

<sup>96</sup> Cf. Pharmig (2011): Arzneimittel und Gesundheitswesen in Österreich. Daten und Fakten kom-pakt. Internet: [http://www.pharmig.at/uploads/Daten\\_und\\_Fakten\\_2016\\_deutsch\\_web\\_15621\\_DE.pdf](http://www.pharmig.at/uploads/Daten_und_Fakten_2016_deutsch_web_15621_DE.pdf) (S. 22, Accessed: 16.11.2017).

*“Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for one year after the initial change was authorised.”<sup>97</sup>*

It is problematic in this context that new significant clinical or pre-clinical studies must be provided for the protection being granted. These are typically not useful or necessary for the actual switch, and such studies are generally not available, particularly considering the finances needed to perform them.<sup>98</sup> So the protection intended as an incentive for manufacturers to submit switch applications is de facto rarely granted in practice. Anticipating this situation, corresponding switch applications regularly fail to appear due to economic considerations of the manufacturers. Recognition of other clinical and preclinical studies must be considered as a practical and effective way to remedy this situation. Maybe data exclusivity would be granted more frequently if economic analyses, studies on the advice in pharmacies or observational studies were taken into account within the evaluation. However, EU law would have to be changed for this.

In addition to the criteria for the recognition of data exclusivity, the duration of the exclusivity period shall also be questioned. Within the Tajani initiative launched in September 2010 a working group entitled “Promoting Good Governance of Non-Prescription Drugs in Europe” stated in its final report that companies would have to be granted the possibility of re-financing their switch investments through data exclusivity. For this purpose a data exclusivity of one year would be insufficient. A period of three years, as practiced in the United States and Japan, was considered credible.<sup>99</sup> The authors of the present expertise have nothing to add to this recommendation.

When looking at technical aspects, it must also be considered that from an enterprise perspective the Austrian pharmaceutical market might seem too small, and that the investment in a switch procedure would only be profitable within an appropriate time horizon. A similar situation can be assumed in other countries with a relatively small pharmaceutical market, so that overall one can speak of a “dilemma of small countries”. One possible approach for the unmitigated and rapid implementation of switches also in smaller markets could be the automatic adoption of switch decisions taken in specific reference or neighbouring countries. For Austria, for example, Germany would be eligible as a reference country due to the

<sup>97</sup> European Commission (2006): A Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use. Article 74a of Directive 2001/83/EC amended by Directive 2004/27/EC. Internet: [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide\\_160106\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide_160106_en.pdf) (Accessed: 16.11.2017).

<sup>98</sup> As a result, the emergency contraceptive EllaOne has so far been the only one that has been granted such a kind of data exclusivity.

<sup>99</sup> Cf. For the procedural aspects of switch procedures see also Kroth, E. (2017a): Switch – Wie steht Deutschland im internationalen Vergleich da? In: Gesundheitsökonomie & Qualitätsmanagement, 51/2017, 22. Jhrg. S. S3–S11.

switch-active character of the country and sufficiently similar surroundings. Another imaginable solution, at least from the perspective of the health care system, could be the initiation of switches by the authorities. The costs of such switch procedures would consequently have to be borne by the national competent authorities. In regulatory terms, this approach would however represent a major interference with the market, entrepreneurial freedom and property rights of the company. At least from the companies’ perspective, this must be viewed critically, as the manufacturer of the switched medicine also has to cope with the economic consequences of this dirigiste intervention in cases where they prove negative.

The EU Commission recently adopted an initiative for “better regulation”. Within this initiative existing legislation shall be evaluated in terms of their relevance and effectiveness with the involvement of stakeholders.<sup>100</sup> Eventually, this initiative may provide the right frame for possible adjustments of given regulations as regards the duration of data exclusivity and the conditions for granting it.<sup>101</sup>

## 4.2 Framework Conditions of the Pharmaceutical Market and the Health Care System as Prerequisites for the Market Success of Switches

The three following Chapters will first describe the factors that have proven to be important internationally for the feasibility and success of switches on the basis of a literature review. Based on these criteria it is subsequently outlined which of these factors are currently regarded as particularly promoting or inhibiting in Austria. This question is only discussed briefly because it is not within the focus of the actual question, namely the identification of switch potentials in Austria. Finally, Chapter 4.2.3 will discuss the special role of pharmacies at the borderline of self-care.

### 4.2.1 Building Blocks of a Positive Switch Climate

Some aspects which have a crucial influence on the switch climate within a country, and by this may provide respective market incentives, were identified and empirically analysed for

<sup>100</sup> Cf. Bundesverband der Arzneimittel-Hersteller (2017): Weniger ist mehr. In: Arzneimittelversorgung in Europa. Handlungsfelder für eine moderne EU-Gesundheitspolitik. Bonn, S. 6.

<sup>101</sup> Cf. Kroth, E. (2017c): Switch – The German process for moving medicines from prescription to non-prescription status. Zur Publikation angenommen in: Gesundheitsökonomie & Qualitätsmanagement, Thieme Verlag. S. S3–S11.



different countries by the internationally renowned switch expert Natalie Gauld. Her work makes clear how crucial the conditions for successful switches are. Whereas Gauld and co-authors examined Great Britain, the United States, New Zealand, Australia and Japan in detail, Canada, Singapore, Denmark, the Netherlands and the European Union served for complementary orientation. Various categories for dispense and switch trends of the countries were used for their selection. It must be taken into account for this that it is usually a combination of various factors which is actually responsible for a successful switch.<sup>102</sup> The following Table (Table 6) provides an overview of the findings of Gauld and co-authors:

	NZL	AUS	UK	USA	Japan
Support by policy/government	0	--	++	-	++/-
Openness of competent authorities and committees for switches	+++	-	++	+/-	+/-
Cooperation of competent authorities	++	-	+++	+++	+
Costs and investments for switch applications	+	+	-	-	
Market exclusivity and transparency	---	--	+	+++	+++
Involvement of pharmaceutical industry	--	+	++	+++/-	+/-
Confidence of industry in the switch committee	++	--	+	+	
Population and market size	---	-	++	+++	
Possibilities of advertisement for OTC	+	--	++	+	+/-
Different rules for dispensing	+++	++	+	--	++/-
Support by pharmacist associations	++	+/-	+++	0	++
Proactive support in single pharmacies	-	-	-	--	--
Support by physician associations	0	--	++/-	+/-	--
Engagement of individual persons	++	+/-	+/-		
Culture of self-medication	+/-		+/-	+++	--
Reimbursement of prescribed medicines	--	+	--	+	--
Refusal of changes/ protection of vested rights	-	--	-	-	---

Table 6: Factors influencing switches<sup>103</sup>

Basically, the support from policy, the government and authorities, existing regional dispense categories in the sense of an existing “pharmacy-only” principle, at least for certain products, as well as large pharma markets due to large numbers of people and the commitment of individuals were identified as key supporting factors. Furthermore, the support for switch

<sup>102</sup> Cf. Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: Pharm. Ind. 79, Nr. 7. S. 927–932.

<sup>103</sup> Own illustration according to Gauld, N. J., Bryant, L., Emmerton, L. et al. (2015 c). The factors that have been identified by the cross-country comparison, which may also influence the switch climate in Austria, are presented here, before they are reflected on in the following Chapter 4.2.2 with focus on the current situation in Austria.

projects from the pharmacist and medical profession plays a decisive role.<sup>104</sup> A key factor is whether the switch candidates are accepted by these stakeholders. In this regard, incentive effects (also of economic nature) are of particular importance for pharmacists and doctors. The British switch expert Anna Maxwell elucidates this with the following statement: “Switch can only work if pharmacists and doctors are on side.”<sup>105</sup> This includes the sales and consulting behaviour of pharmacists, and the willingness of physicians to have confidence in consumers and pharmacists with regard to self-care with OTC medicines and to shift a small part of their competencies in the direction of pharmacies. Last but not least, the remuneration system of the physicians also plays a role in this context.<sup>106</sup> Regardless of these aspects, fast and inexpensive processes further promote the readiness of manufacturers for switch applications.<sup>107</sup>

Obstructive factors for the switch climate include an unhindered access to physician care, associated with an inexpensive or free receipt of medicines via prescription, as well as the cessation of reimbursement associated with a switch. This is further influenced by consumer behaviour regarding doctor consultations, in particular in the case of minor health problems. Additional obstacles for switches are the availability outside pharmacies or the absence of the option to restrict the dispense of products to pharmacists.<sup>108</sup> This applies particularly to active substances for symptom-free problems such as high LDL cholesterol levels, which therefore require more intensive monitoring than easier-to-use ingredients.<sup>109</sup> Specifically for the EU, the widely varying national rules for dispense and the risk-averse behaviour of switch committees were identified as impairing the switch climate. The latter is crucially influenced by the composition of the committees and the need to create a consensus with regional authorities and governments (e.g. in the case of Austria and Germany, the Federal States). Moreover, restrictions on the advertising opportunities for newly switched medicines have proven to be unfavourable for the switch climate. The market exclusivity, based on data exclusivity, of only one year within the EU is regarded as too short and therefore also considerably impedimentary.<sup>110</sup> This is fixed in a uniform way across the EU by existing EU law.<sup>111</sup>

In general, pricing mechanisms and the reimbursement of OTC medicines can have a great impact on the switch climate of a country. The development of OTC prices is particularly influ-

<sup>104</sup> Cf. Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: Pharm. Ind. 79, Nr. 7. S. 927–932.

<sup>105</sup> Wilkes, D. (2015a): Switching hinges on changing behavior. Internet: <http://www.otctoolbox.com/news/switching-hinges-on-changing-behaviour.aspx> (Accessed: 16.11.2017).

<sup>106</sup> Cf. May, U., Bauer, C. (2017): Apothekengestützte Selbstbehandlung bei leichteren Gesundheitsstörungen – Nutzen und Potentiale aus gesundheitsökonomischer Sicht. In: *Gesundh ökon Qual manag* 2017; 22: S12–S22.

<sup>107</sup> Cf. Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: Pharm. Ind. 79, Nr. 7. S. 927–932.

<sup>108</sup> Cf. *ibid.*

<sup>109</sup> Cf. Wilkes, D. (2015 c): New Ideas Better Ways. Making commercial sense of switching. In: *OTCToolbox Innovations*, Edition 5. Internet: <http://www.imsconsultinggroup.com/files/web/Corporate/News/In%20the%20News/OTCToolboxArticle.pdf> (Accessed: 29.11.2017).

<sup>110</sup> Cf. Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: Pharm. Ind. 79, Nr. 7. S. 927–932.

<sup>111</sup> Cf. European Commission (2006): A Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use. Article 74a of Directive 2001/83/EC amended by Directive 2004/27/EC. Internet: [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide\\_160106\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/switchguide_160106_en.pdf) (Accessed: 16.11.2017).

enced by the question of whether the same product can also be prescribed and reimbursed. This in turn affects the willingness of consumers to treat mild health problems independently and at their own expense. Based on this knowledge, appropriate mechanisms at the national level can be designed as promotive or obstructive for a switch.<sup>112</sup>

Due to various combinations of the above mentioned factors, potential OTC markets pose different challenges to pharmaceutical companies globally. Various successes and failures of past switches show that it is difficult to appraise these factors in advance. The option of centralised switches in the EU is considered in particular to be disappointing with a view to the results so far, especially with regard to the number of switched products and the associated financial success. Moreover, it is questionable why successful switches, that even after ten years have not been withdrawn, are not adopted by other countries.<sup>113</sup> In this context, reference shall be made to the "dilemma of small countries" described in Chapter 4.1.2 which could be counteracted through intensified EU wide switches and automatic adoption of implemented switches after a certain period of time.

The question of whether a switch is reasonable from the perspective of health economy by promoting self-care in a medically acceptable range of indications, must in principle be evaluated separately from the business perspective of the respective pharmaceutical company. However, both have one central basic prerequisite for a positive impact in terms of the entrepreneurial or the health-economic success in common, i.e. that the indication areas of the „switched“ product are all recognised in the market and thus by consumers as possible areas for self-medication. The European and the US-American market provide a number of examples of attempts to open up new indication areas for self-medication, which were successful from the business perspective (e.g. heartburn, allergies) or also failures (e.g. Lipitor (atorvastatin) in the United States). In this regard, the acceptance of the switch candidate or indications by opinion leaders and especially by health care experts shall in turn be emphasised as a key factor.<sup>114</sup>

To come full circle: A switch policy which is integrated in a self-care friendly framework can ultimately make OTC switches also more interesting from a company perspective and by this resolve the given conflict of interests and objectives. In a legal framework such as the current one in Austria this is in turn the prerequisite that switch applications which are health-economically desirable are undertaken by companies.

<sup>112</sup> Cf. Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: Pharm. Ind. 79, Nr. 7. S. 927–932.

<sup>113</sup> Cf. Wilkes, D. (2015 c): New Ideas Better Ways. Making commercial sense of switching. In: OTCToolbox Innovations, Edition 5. Internet: <http://www.imsconsultinggroup.com/files/web/Corporate/News/In%20the%20News/OTCToolboxArticle.pdf> (Accessed: 29.11.2017).

<sup>114</sup> Cf. Wilkes, D. (2015 c): New Ideas Better Ways. Making commercial sense of switching. In: OTCToolbox Innovations, Edition 5. Internet: <http://www.imsconsultinggroup.com/files/web/Corporate/News/In%20the%20News/OTCToolboxArticle.pdf> (Accessed: 29.11.2017).

## 4.2.2 Starting Points for a Pro-switch Policy for Austria

Considering the conditions of the Austrian medicines and health care system in light of the above-described international findings regarding a positive switch climate, there are some striking positive and negative aspects. Targeting a pro-switch policy, the identified positive aspects are to be maintained and expanded, while the negative aspects indicate the need for modification or reforms.

Among the **switch-promoting conditions**, some regulations in the pharmacy sector shall be emphasised foremost. The present pricing system provides no negative financial incentive for pharmacists to prefer the dispense of Rx medicines. The restriction of the dispense of OTC products to pharmacies only is also supportive for OTC switches. Accompanying this, the relatively liberal advertising regulations can help new OTC preparations to gain popularity quickly and enable industry to promote their sale by pharmacies.<sup>115</sup> As a restriction, however, it must be stated that the attitude of Austrian pharmacists towards the switch issue is rather restrained, which according to empirical findings represents a significant inhibiting factor for switch successes. The importance of the openness of involved authorities and the commitment of individuals should not to be underestimated either. In this respect the BASG and the Agency for Food Safety (AGES) contribute positively to the switch climate in Austria.

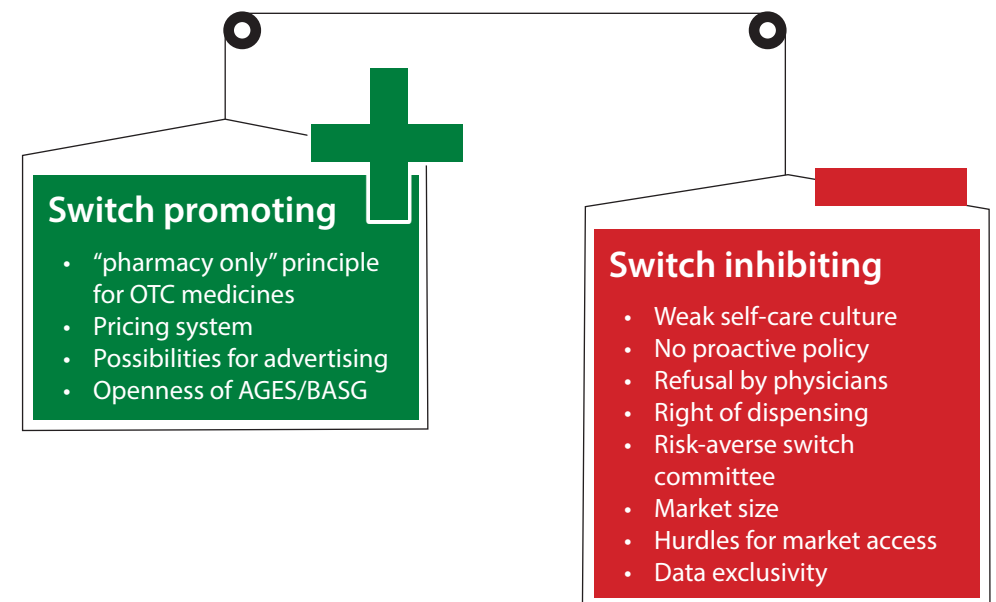


Figure 22: Promoting and inhibiting factors for switches in Austria

<sup>115</sup> It is important in this context that the advertising possibilities for OTC medicines should also be maintained if they can be partly reimbursed.

Some OTC products can currently be prescribed and reimbursed in Austria. This situation results in the incentive for Austrian consumers to go to the doctor being relatively high in such cases where consumers, for example, in the United Kingdom, Germany, Switzerland and above all the United States would purchase a non-refundable OTC. This is especially true for those patients who do not have to pay the prescription fee. On the basis of the international empirical research by Gauld et al. such a situation would have to be classified clearly as a switch inhibiting factor. When placing special focus on Austria, ambivalent effects of this rule may be assumed. Switches penetrate the market faster, in the sense of a depth effect for self-medication, if full refunding is excluded. In contrast however, Rx-to-OTC switches accompanied by mandatory exclusion from reimbursement also acquire a distribution-related and socio-political dimension. Particularly in light of the social-democratic tradition of Austria, and the weakly pronounced self-responsibility culture of the country, this can represent an important hurdle in gaining political and administrative support for switch projects.

It fits well into the picture of the switch-backlog identified in this study that the list of identified factors that are rather switch hampering in Austria is much longer than the one with the switch promoting factors. Of far-reaching importance is the fact that there is virtually no political backing and certainly no proactive support for the topics “self-care” and “switch” in the republic. The matter has up to now not found an adequate place on the political agenda. This leads to consequences that are reflected in the legislation in various relevant areas. Last but not least, the impact of the design of regulatory and health policy has so far prevented the development of a culture in which (health) self-responsibility and self-care could prosper as far as possible. Today, as a result, a certain “comprehensive insurance mentality” and the readiness to see a doctor at relatively minor occasions are still relatively strongly developed in comparison to other countries. The organised medical profession further feeds this mentality by attributing more risks than benefits to self-medication. This sceptical attitude also characterises the relationship of practising physicians to non-prescription medicines and their advice patterns.<sup>116</sup> Case number-related remuneration is a major reason for this attitude of the medical profession; and may also serve as a concrete, though complex starting point, for the creation of a better switch climate.

The right to dispense serves as a further stumbling block for switches based in the medical sector. It offers a further economic (false) incentive against self-care, through additional remuneration for the dispensing doctors. Moreover, the dispense of medicines in the physician's office creates a comparative disadvantage for self-care, because the patients can save

<sup>116</sup> Cf. auch Ostermann, H., Renner, A.-T., Bobek, J. et al. (2015): A cost/benefit analysis of self-care systems in the European Union. Final report. Internet: [https://www.google.de/url?sa=t&rc=1&ct=1&esrc=s&source=web&cd=1&ved=0ahUKewiE-KbX3ePXAhU-HaFAKHSL9DLcQFggrMAA&url=https%3A%2F%2Fec.europa.eu%2Fhealth%2Fsites%2Fhealth%2Ffiles%2Fpatient\\_safety%2F-docs%2F2015\\_selfcaresystemsstudy\\_en.pdf&usq=AOvVaw1wGGx21NJF\\_1cVHkkPPIG2](https://www.google.de/url?sa=t&rc=1&ct=1&esrc=s&source=web&cd=1&ved=0ahUKewiE-KbX3ePXAhU-HaFAKHSL9DLcQFggrMAA&url=https%3A%2F%2Fec.europa.eu%2Fhealth%2Fsites%2Fhealth%2Ffiles%2Fpatient_safety%2F-docs%2F2015_selfcaresystemsstudy_en.pdf&usq=AOvVaw1wGGx21NJF_1cVHkkPPIG2) (Accessed: 29.11.2017).

the time required for a pharmacy visit.<sup>117</sup>

Factors that are not accessible to such measures, but can be better compensated with appropriate arrangements, include the size of the Austrian population and the resulting relatively small market size. This factor, which was described in Chapter 4.1.2 as the “dilemma of small countries”, could be relativised by intensified EU-wide switches or an automatic adoption of implemented switches after a certain period of time.

A further obstacle to switches, which is however not Austria-specific, but affects the whole EU, is that based on the switch-guideline where the data exclusivity period which can be granted for a switch application is restricted to only one year. In Austria the decision whether to do so or not is taken by the Federal Office for Safety in Health Care (BASG), based on EU rules. In addition to the restrictive criteria for the recognition of data exclusivity, the duration of the exclusivity period is also deemed insufficient. To make a switch attractive for an applicant company, a period of three years, as practiced in the United States and Japan, would rather be assessed as reasonable.

In addition to the question of whether switch applications are to be submitted and succeed on the market, the decision-making of the switch committee de facto also constitutes a major hurdle. A risk-focused attitude of switch committees often prevails, not only in Austria. Based on the considerations of Chapter 3.2.4 a broader approach to balancing benefits and risks should be applied that takes the supply- and scarcity-related risks as much into account as application- and substance-related risks.

In addition to the above mentioned individual aspects that can be switch inhibiting or switch promoting, consumer-held information status and low-threshold access to quality-assured information play a central role when it comes to the existing demarcation, as well as an eventual shift of the limitations, of medically acceptable self-care. In recent decades, the international switch movement has followed the increasing health education of the population which has partly lead to switches that would not previously have been justifiable. The increasing information resources offered on the Internet and their increasing use by consumers of all age and population groups (“Dr. Google”) has pushed the dynamics of this development in Austria and elsewhere. This can especially help to expand the self-diagnosis and self-care ability of medical laypersons beyond former restrictions, if the contents of the available or created information resources are quality-assured. Due to the expected rapidly progressing digitalisation and allround availability of processed data, also in the form of diagnostics tools,

<sup>117</sup> From the patient perspective the situation presents as follows: in the case of a health disorder he compares the investment and benefit for a physician consultation with those of self-care. The dis-pense right would constitute a “plus-point” for the doctor visit, as the time investment for the visit to the pharmacy is omitted; what is an advantage for this option is necessarily a disadvantage for the alternative option, here self-care.

this trend could even accelerate significantly in the future.<sup>118</sup> To give an example, at the beginning of 2016 partners from The Netherlands and Germany launched a cross-border project to strengthen telemedical innovations in the health care industry. The project entitled “MIND” is also expressly intended to promote fast help for patients and their “self-management”.<sup>119</sup>

The special role of pharmacies, also in the context of an appropriate funneling of the flood of information for the individual patient, is discussed in the following Chapter.

### 4.2.3 The Role of Pharmacies at the Borderline of Self-care

Switches, especially innovative switches, are naturally at the borderline of what has so far been deemed accessible to self-care in a respective health care system.

As surveys on the subjective perception of consumers show, above all, pharmacies can close the knowledge and confidence gaps that may impede self-care. Prevailing demoscopic studies have demonstrated that the Austrian population places such great confidence in pharmacists that they are predestined to assume this responsible task.<sup>120</sup> The low-threshold access to care offered by pharmacies allows the consumer to achieve his objective, namely to minimise his investment for treatment. With this background, it is evident that pharmacies nowadays determine how consumers estimate the expected benefits, risks and costs of self-care. This in turn provides the basis for the decision of whether the consumer takes treatment with a newly available non-prescription product into consideration as an alternative to seeing a doctor. Empirical findings suggest that, in many cases, pharmacies are the ultimate source of the impulse of consumers to choose the route of self-care.

However, pharmacies are not only important when considering the readiness for self-care, but also for its success and safety. Particularly in the area of self-care, a high quality of advice is characterised by the validity and completeness of advice as well as the mutual exchange of information. The aim is to make decisions in a cooperative process, which takes place between the pharmacist and the patient, and takes patient competence regarding the respective health issue (“shared decision making”) into special account. In the area of self-care this is of particular significance because here the advice includes a “triage” function: if necessary, the patient must be advised to consult a doctor. This would be cost-effective. In the reverse case, considerable costs can often be saved.<sup>121</sup>

<sup>118</sup> Cf. Carl, M. (2016): Zukunftsmarkt Gesundheit: Apotheken der Zukunft – Den Wandel gestalten – Keynote beim 8. Zukunftskongress Öffentliche Apotheke des Apothekerverbands Nordrhein e. V., World Conference Center Bonn am 13.02.2016.

<sup>119</sup> Cf. Blasius, H. (2016): Digitale Gesundheit. Grenzüberschreitendes Projekt will Telemedizin fördern. In: DAZ Online. Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2016/02/17/grenzuberschreitendes-projekt-gestartet> (Accessed: 16.11.2017).

<sup>120</sup> Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.

<sup>121</sup> Cf. May, U., Bauer, C., Dettling, H.-U. (2017): Versandverbot verschreibungspflichtiger Arzneimittel. Stuttgart 2017.

Hence the restriction of dispense to pharmacies, which is applicable to most OTC medicines, is an immediate and consistent expression of the fact that from the perspective of the legislative authorities, the limits of self-care with pharmacy support can be set wider than would be possible without the participation of healthcare professionals. So, the personal contact between the patient and pharmacist on site is in many cases an important basis for the functioning and success of self-medication. This is especially true with regard to the prevention of possible dangers that might otherwise be incurred in the course of an expansion of the spectrum of self-medication.

A recommendation of the competent Committee of the German Federal Council in the case of the “morning-after pill” provides an argumentative blueprint in the context of these considerations, which can also be seen detached from the specific case and in terms of more innovative switches:

*„in case of a respective dispense rule (Note: non-prescription status) in the Federal Republic of Germany more emphasis would be placed on the consulting expertise of pharmacies, as based on the ‘pharmacy-only principle’ they must inform properly about risks, side effects and correct administration. As practitioners of a scientifically based health profession, pharmacists are optimally qualified. They are not only able to guarantee safe dispensing of emergency contraceptives, but due to their advisory skills predestined to convey the factual information necessary for application, adjusted to recipients and situations“<sup>122</sup>*

In a decision of the German Federal Council the following is stated in the same context:

*„The restriction of the dispense of the medicine to pharmacies ensures the necessary competent advice for patients, also after release from the prescription requirement, including, where appropriate, the referral to a doctor“<sup>123</sup>*

Pharmacist organisations, and at least parts of health policy, assess the experience gained so far with the OTC status of the “morning-after pill” as proof of a successful expansion of the tasks of pharmacists.<sup>124</sup> Based on this experience, further “competence extensions” for pharmacists are claimed, partly also in Austria.<sup>125</sup>

<sup>122</sup> Bundesrat (2013): Beschluss des Bundesrates. Entschließung des Bundesrates zur Rezeptfreiheit von Notfallkontrazeptiva auf der Basis von Levonorgestrel – Pille danach – Drucksache 555/13 (Beschluss) 05.07.2013.

<sup>123</sup> Ibid.

<sup>124</sup> Cf. Preis, T. (2016): Podiumsdiskussion beim 8. Zukunftskongress Öffentliche Apotheke des Apothekerverbands Nordrhein e. V., World Conference Center Bonn am 13.02.2016.

<sup>125</sup> Cf. Steffens, B. (2016): „Grußwort Politik“ beim 8. Zukunftskongress Öffentliche Apotheke des Apothekerverbands Nordrhein e. V., World Conference Center Bonn am 13.02.2016.

Cf. APA OTS (2016): Apotheken wollen mehr Dienstleistungen anbieten. Internet: [https://www.ots.at/presseaussendung/OTS\\_20160610\\_OTS0083/apotheken-wollen-mehr-dienstleistungen-anbieten-bild](https://www.ots.at/presseaussendung/OTS_20160610_OTS0083/apotheken-wollen-mehr-dienstleistungen-anbieten-bild) (Accessed: 16.11.2017).



With a view to the relief of resources in the ambulatory care sector it should also be pointed out that the success and scope of self-medication depends to a large extent on the low-threshold and nationwide access to pharmacies and the advice provided there.<sup>126</sup>

An investigation by the consultancy firm PricewaterhouseCoopers, on behalf of the British Government, found that pharmacy services brought savings of GBP 3 billion to British health-care in 2015. With a share of 40%, the support of self-care accounted for the largest contribution to the total, followed by medicines management (31%) and public health (29%).<sup>127</sup> Calculations for Germany also confirm a high share of health-economic added value attributed to pharmacies in self-medication.<sup>128</sup>

The previous Chapter has already addressed the increasing importance of information from the Internet for the Austrian consumer in terms of self-medication. In the majority of cases however, online research as well as information from literature or from self-help groups will be only a first step within the search for information. For the grading of the collected information, the assessment with a view to the actual personal situation, and for reconfirmation or review of an individual decision, the personal exchange with a health care professional will be required or desired in many cases. Better informed consumers naturally increase the challenges to the pharmaceutical competence in pharmacies and may sometimes be more challenging. It seems logical that an increasing number of pharmacy clients will expect evidence-based statements on the patient-relevant benefits of self-care. On-site pharmacies can offer a personal conversation which provides information focusing on the individual person, eventually linked to an OTC recommendation. Ideally, the offer provided by pharmacies should consider the „*health, emotional and intellectual conditions of the patient as well as his social and economic situation*“.<sup>129</sup>

In light of the need for intensified involvement of pharmacies in giving the advice necessary for newly switched medicines, the borderline for self-care must not be drawn statically, and the fact that the professional obligations of pharmacists can be adapted adequately should be borne in mind. Moreover, it should leave room for successive developments and “cross-border” initiatives. Following individual initiatives and examples of other European countries (United Kingdom, Switzerland, The Netherlands, Italy), pharmaceutical tasks in the area of self-care can be designed with a broader scope and the limits of self-care consequently expanded by switches. An exchange between the presidents of pharmacist organisations

<sup>126</sup> Cf. May, U./ Bauer, C. (2016): Selbstbehandlung und Apotheke. Gutachten im Auftrag des BAH. Bonn 2016.

<sup>127</sup> Cf. Pricewaterhouse Coopers (2016): The value of community pharmacy – detailed report. September 2016. Internet: <http://psnc.org.uk/wp-content/uploads/2016/09/The-value-of-community-pharmacy-detailed-report.pdf> (Accessed: 16.11.2017).

<sup>128</sup> Cf. May, U. (2013): Selbstmedikation in der Apotheke: Neue Erkenntnisse aus gesundheitsökonomischer Sicht. Präsentation beim OTC-Gipfel 2013 des Apothekerverbands Nordrhein, Düsseldorf, 16.10.2013.

<sup>129</sup> Pfeifer, J. (2014): Evidenzbasiert gut beraten. In: Pharmazeutische Zeitung. 159. Jahrg. Nr. 38. Eschborn 2014, und Pfeifer, J. (2014a): German Community Pharmacists: From Product-Oriented Suppliers to Patient-Oriented Health Care Professionals. Baden-Baden 2014.

from Austria and further German-speaking countries, at the Pharmacon early in 2016, revealed that opportunities to redefine the role of pharmacies not only exist but can be practically implemented and actively promoted by pharmacists.<sup>130</sup> This applies in particular to the existing potential for intensifying the pharmaceutical advice and support for self-medication by means of structured conceptual elements, to systematically minimise errors and by this to optimise OTC advice.<sup>131</sup> The success of such measures for self-medication has already been investigated and acceptance by the patients been described.<sup>132</sup> Numerous findings on this have recently been obtained, especially in the Anglo-Saxon region. These approaches could systematically also help to expand the function of the pharmacy as a gatekeeper and first point of contact for people with minor health problems. With the aid of legitimised medical and pharmaceutical catalogues of criteria for the demarcation of reasonable self-care and the referral to a physician in predefined cases, the limits of self-care could be better exploited and at the same time better adhered to.<sup>133</sup> In the end, this option helps to better explore the individual limits of self-care at a higher level and to minimise the risk that these limits are exceeded at the expense of the consumer.

Despite promising, already implemented approaches, the tasks and functions of pharmacies can still be significantly expanded in this context. Illustrative practice-proven examples can be found in other European countries, in particular in the Anglo-Saxon countries, and partly in Switzerland. For example, regarding OTC switches of certain vaccines, as they were discussed in the visionary switch proposals in Chapter 3.3.2, an extension of the competence of pharmacies with respect to the administration of these vaccines should also be discussed. Positive evidence-based experiences with this option have already been collected internationally.<sup>134</sup>

<sup>130</sup> Cf. Apotheker Zeitung (2016): Neue Rolle für die Apotheker gesucht. Apotheker Zeitung, 32. Jahrgang, vom 25.01.2016, S. 1 und S. 8

<sup>131</sup> Cf. Laven, A., Schäfer, J., Läer, S. (2014): PHARMAGRIPS: Pharmazeutische Beratung in der Selbstmedikation des grippalen Infekts. Eine randomisierte kontrollierte Studie (RCT). Med. Mo. Pharm. 37 (6) (2014) S. 209–220 und Pfeifer, J. (2014): Evidenzbasiert gut beraten. In: Pharmazeutische Zeitung. 159. Jahrg. Nr. 38. Eschborn 2014.

<sup>132</sup> Cf. Krishnan, H. S. (1999): Analyse und Bewertung der Beratungstätigkeit der Apotheke in der Selbstmedikation dargestellt am Beispiel dyspeptischer Beschwerden. Dissertation. Berlin 1999.

Cf. Paudyal, V., Watson, M. C., Sach, T. et al. (2011): Pharmacy assisted patient Self-care of minor ailments: a chronological review of UK health policy documents and key events 1997–2010. Health Policy 101(3), S. 253–259.

Cf. Schaefer, M. (2001a): Patienten wünschen sich Pharmazeutische Betreuung. In: Pharm. Zeitung 146 (2001) 11, S. 854–858.

Cf. Schaefer, M. (2001b): Pharmaceutical Care. In: Pharmazeutische Praxis (Hrsg. Kovar, K.-A.), Deutscher Apotheker Verlag 2001.

<sup>133</sup> These efforts are reinforced by the creation of incentive-adjusted conditions, as they are used in the British Minor Ailment Schemes. In this context Pfeifer emphasises that remuneration of the pharmacist service exclusively via the retail price of a medicine, as it is currently practiced in Germany, implies the danger of getting into a conflict with the status of the pharmacist as a health professional that may also require the refusal of an OTC purchase.

Cf. Pfeifer, J. (2014): Evidenzbasiert gut beraten. In: Pharmazeutische Zeitung. 159. Jahrg. Nr. 38. Eschborn.

<sup>134</sup> Cf. Gauld, N. (2017): Switch and pharmacist-supply: a view from abroad. Vortrag im Rahmen der ersten Switch-Konferenz des BAH am 06.07.2017.

## 5 Perspective-adjusted Assessment

The effects associated with switches partly affect the social and economic level, but an appropriate disaggregation of the benefit and cost types also allows the focus on more restricted perspectives of other stakeholders. In this Chapter the most important individual perspectives on the topic “switch” are represented, followed by the perspective of society.

### 5.1 Extended Self-care and Switches from the Perspective of Stakeholders

The following Figure 23 shows the key stakeholders who are directly affected by OTC switches (or waivers of switches).

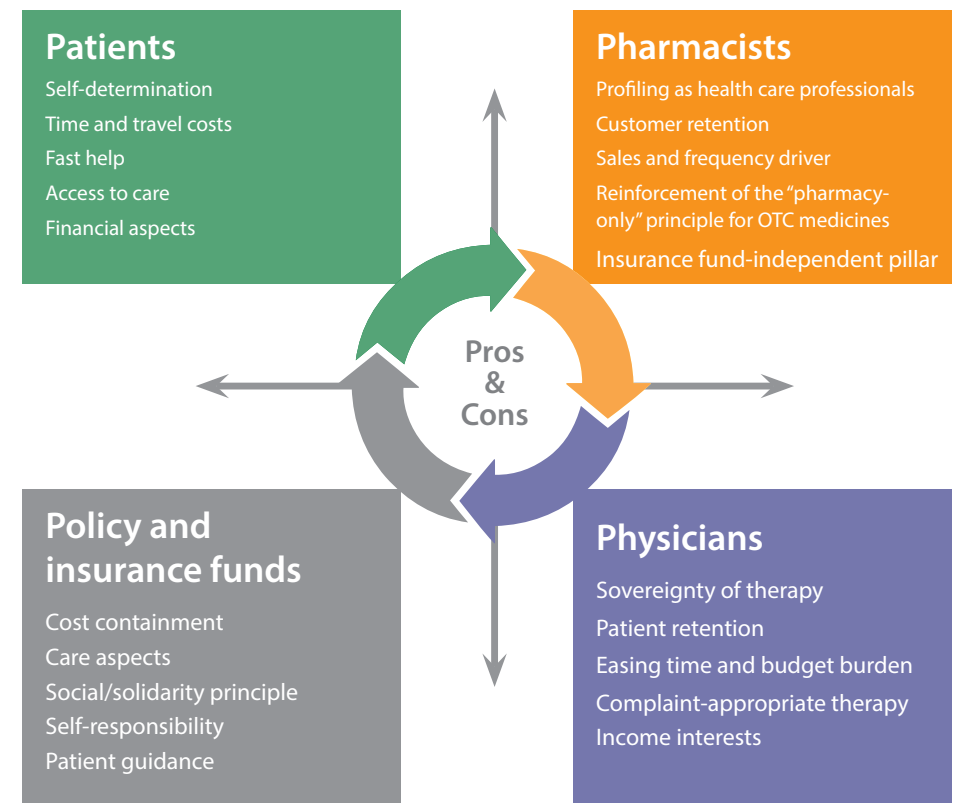


Figure 23: Self-care and switches: perspective of stakeholders<sup>135</sup>

<sup>135</sup> Adapted to: May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.



First and foremost the patients, and secondarily the pharmacists and/or physicians, are involved in the treatment process. Policy and health insurance funds partly provide the framework for this process and are, as a result, confronted with the financial and economic consequences of switch decisions. Pharmaceutical companies, acting as applicants and profiting beneficiaries, as well as the Commission on Compulsory Prescription and authorities, as decision-making bodies, assume special roles that go beyond this. The individual perspectives of stakeholders on the topic of “switch” are described below.

### 5.1.1 Consumers and Patients

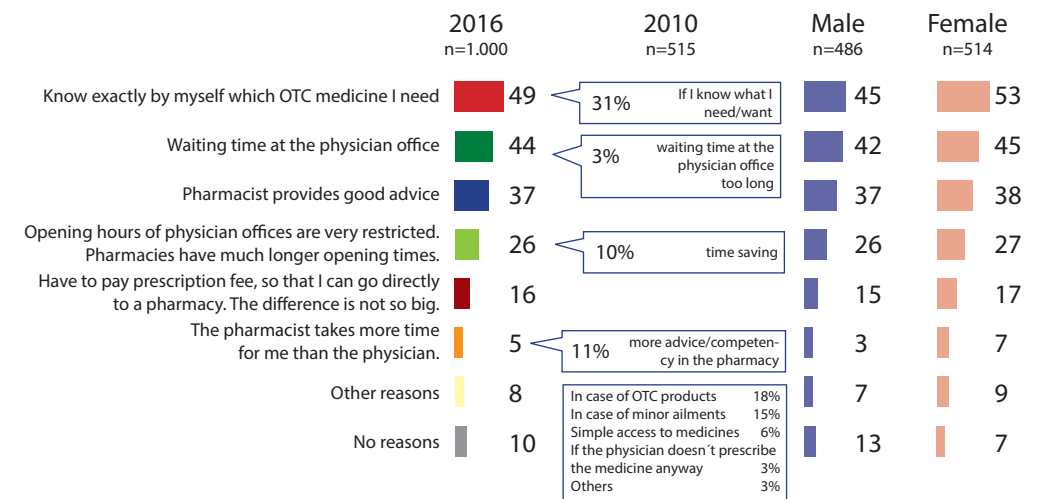
With a view to the acceptance of self-medication by Austrian consumers, which has been recorded through purchases and documented by demoscopic results<sup>136</sup>, it can firstly be stated without any further differentiation that the use of OTC medicines makes a positive contribution to the quality of life of the average user and by this has an intangible benefit. This is demonstrated by high repurchase rates and the documented satisfaction with purchase decisions. Studies, not only from Austria, but also from many other countries, show that consumers attribute a great benefit and high efficacy to their purchased OTC medicines.

If the availability of over-the-counter medicines and the opportunities for self-medication are widened through switches, this represents an extension of the scope of action for the patient, which is basically positive. This is especially true for the given regulatory background in Austria, according to which a switch does not typically restrict the option of seeing a doctor or the possibility of getting a medical prescription for the medicine. Whether the patient chooses this option in an individual case, depends on his individual decision calculation. This calculation covers the expectations of patients regarding the benefits and possible risks which they associate with self-medication or a possible physician consultation. If self-care is deemed acceptable under these conditions, monetary considerations, time and travel costs, as well as some intangible effects become relevant for the decision. For self-medication, the latter include the value that is attributed to self-determination, as well as the convenience and fast access to the solution for the problem.

Based on a health economic study, the time and monetary aspects can also be estimated for a single case from the perspective of an individual.<sup>137</sup> According to these calculations, the cost for a case of self-medication<sup>138</sup> amounts to an average of EUR 10.06. This contrasts to the

currently fixed prescription fee of EUR 5.15<sup>139</sup>, if the medicine is prescribed. However, due to exemptions from co-payment based on social law, the average co-payment is only EUR 3.22. The statistical average of the difference between these two amounts is EUR 7.00 to the disadvantage of self-medication. The consultation with a physician is generally not associated with any costs to patients in Austria. Hence, in the reverse conclusion, the patient has no individual or direct benefit from the avoided physician costs. Consequently, the monetary comparison between visiting a doctor and self-medication, based on the statistical average, can be summarised in the following formula: a patient who exercises self-medication saves an average amount of EUR 52.49 for the health care system, but is charged more himself with a statistical mean of EUR 7.00 for medication costs.

From this individual calculation, only the mentioned intangible effects, in particular the time and travel costs, can determine the decision for self-treatment. In this case, the average of 22 minutes that must be estimated for visiting a pharmacy including travel times and the service in the pharmacy, stand in contrast to an average of 85.5 minutes for a combined doctor and pharmacy visit in Austria. How a person rates this time gain of more than an hour in the case of self-medication and appraises it in relation to his additional expenses, depends to a large extent on the individual. Here, it might also play a role, whether the patient has to invest the time in his spare time or during his work time, and whether an employed worker connects the physician consultation with the prospect of a certificate of incapacity for work.



Question A21: There may be different reasons why people go directly to a pharmacy without prior consultation of a physician. Which of these reasons apply to you?  
Basis: total

Figure 24: Reasons for pharmacy visit<sup>140</sup>

<sup>136</sup> Hereinafter particular reference is made to the results of the most recent GfK survey. Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.

<sup>137</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.

<sup>138</sup> Based on data of the study year 2012.

<sup>139</sup> The figures reflect the status quo at the time of compilation of the study (2017).

<sup>140</sup> GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPA. Wien 2017.

The very high importance attributed by the consumer to the aspects of time and convenience is underpinned by the just cited GfK survey. In this survey 75% of respondents indicated that in the case of a minor health disorder they would directly visit a pharmacy, without consulting a physician beforehand. The most frequently given reasons included the saved waiting time at the physician office, previous experiences with the respective minor disorder so the patient therefore knew which medicine he needed, that the complaints were only minor and that the interviewed person would only see a doctor if he was really ill, and that competent staff would be available in the pharmacy, providing very good advice.<sup>141</sup> Consumers understand minor health disorders above all to comprise common cold, pain (head, muscles, joints, back), digestive problems, heartburn, itching and flu. Every fifth to every eighth respondent also regarded stress, sleep disorders and bronchitis as a minor condition.<sup>142</sup>

More general accompanying effects attributed to self-care, are that together with the increase of personal responsibility, health awareness, consumer sovereignty and general patient participation („*patient empowerment*“) also increase, which must likewise be considered as an intangible benefit.<sup>143</sup> The WHO also advocates this development of patient empowerment, stating: “*Patient empowerment is a process through which people gain greater control over decisions and actions affecting their health and should be seen as both an individual and a community process.*”<sup>144</sup> Obviously switches are also beneficial in this context in the interest of consumers.

One of the most important effects, which from the consumer and patient perspective is directly connected to a switch, relates to access to care and the resulting impact on the quality of care. A low-threshold access to care often has the effect that an adequate treatment is actually used, as having been explained theoretically in Chapter 3.2.2 and illustrated in Chapter 3.3 with reference to innovative switches. Only in this way can a concerned person benefit from this treatment. Migraine treatment was given as an example. There is currently a high degree of undersupply of triptans. It can be expected that patients suffering from migraine will often not find their way to see a doctor, or they would not burden themselves with the physician consultation. Early self-care leads to high gains in terms of health-related quality of life, which has also economic implications (e.g. losses of working hours).

<sup>141</sup> Cf. *ibid.* The percent figures given for the responder statements were taken from a similar GfK survey of 2010.

<sup>142</sup> Cf. *ibid.*

<sup>143</sup> Cf. z. B. Reibnitz, C. v., Litz, D. (1999): Konsumentenstärkung im Gesundheitswesen: Ein großer Schritt zu mehr Demokratie und Effizienz. In: Pharmazeutische Zeitung. 144. Jhrg. Nr. 7. Eschborn 1999. S. 15 – 16.

Cf. z. B. Ostermann, H., Renner, A.-T., Bobek, J., Schneider, P., Vogler, S. (2015): A cost/benefit analysis of self-care systems in the European Union. Final report.

<sup>144</sup> World Health Organization – WHO. World Alliance for Patient Safety. Global Patient Safety Challenge 2005–2006: [http://www.who.int/patientsafety/events/05/GPSC\\_Launch\\_ENGLISH\\_FINAL.pdf](http://www.who.int/patientsafety/events/05/GPSC_Launch_ENGLISH_FINAL.pdf) (Accessed: 16.11.2017).

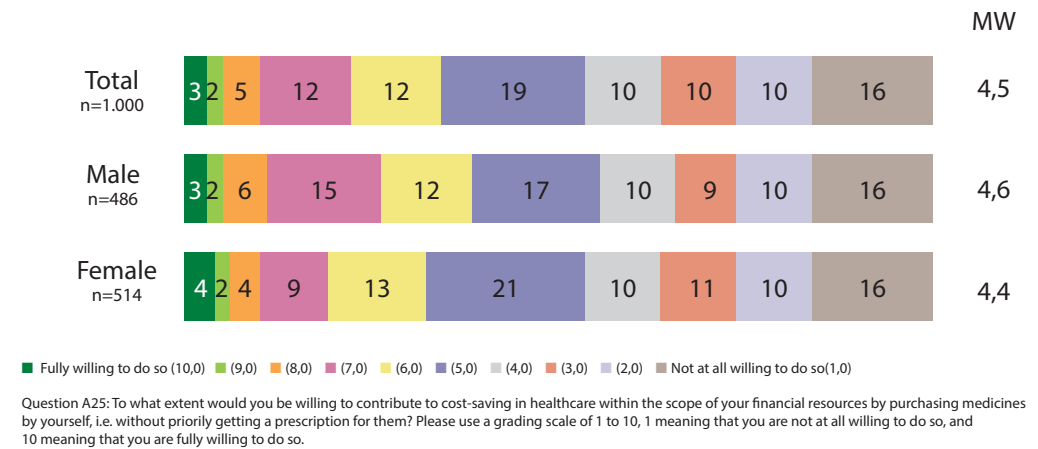


Figure 25: Taking burden from the health care system as a motive for self-care<sup>145</sup>

Many Austrians obviously recognise a correlation between their own behaviour and that of society, and link it positively to a self-responsible health behaviour. As can be seen in the graphical illustration of the survey results (Figure 25), patients are basically aware of the fact that the health care system is facing various difficulties. More than one in three respondents to the GfK poll would already be willing to save costs for health care through the self-purchase of medicines, while a further fifth of the respondents would at least not completely shut themselves away from it. With a view to the actual chances of switches being successful in the market, one piece of empirical evidence should be emphasised, i.e. that those consumers who previously stated that they would not see the doctor first for monetary reasons, are inclined to do so if the costs amount to an average of EUR 16.50 or above.<sup>146</sup>

Admittedly, there appears to be an information deficit among Austrian consumers concerning the risks and safety of non-prescription medicines, which is relevant in the switch context. Almost 60% of the respondents are of the opinion that non-prescription medicines have as many side effects as prescription medicines. In fact, however, the release of a substance from compulsory prescription status should be assessed as a sign of a very positive risk-benefit ratio, good tolerability and a high safety of use for the medicine. Barely 30% of the respondents were aware of this.<sup>147</sup> It can also be expected in this context that – as shown in Germany – consumers similarly assume that a medicine which is available without prescription is less effective than a prescription medicine.<sup>148</sup> It must be presumed that the aforementioned lack

<sup>145</sup> GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPHA. Wien 2017.

<sup>146</sup> Cf. GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPHA. Wien 2017.

<sup>147</sup> Cf. *ibid.*

<sup>148</sup> Cf. YouGovPsychonomics (2011): OTC-Monitor Schlaglicht 2011: Ergebnisse einer Befragung von 1.000 Bundesbürgern zum Verhalten und zur Einstellung gegenüber OTC-Präparaten. Köln 2011.

Cf. Icon Added Value (2006): Apotheker, Arzt und die Selbstmedikation. Emotionale und rationale Leistungswahrnehmung aus

of information can adversely affect the perception and expectations of the population with regard to switches and also their success in Austria.

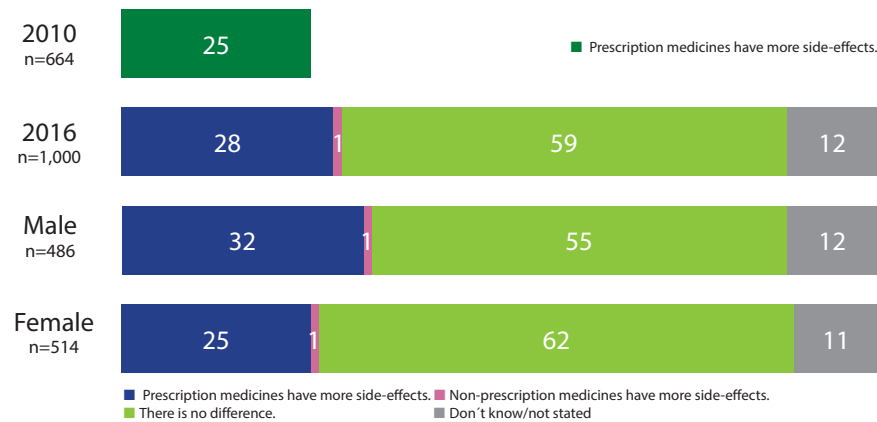


Figure 26: Side effects of Rx and OTC medicines from the perspective of patients<sup>149</sup>

Looking at the patients as a whole somewhat approximates a social perspective. From this point of view, the patients in their entirety benefit at least indirectly from the aggregated direct and indirect cost savings being achievable through self-medication for the health system, consequently reducing the budget they themselves have to finance with their contributions. At this aggregate level, the financial relationships that have been calculated in the frequently cited health economic study for Austria will take effect for patients. An additional effect was explained in this study, i.e. that self-medication practiced by society frees up significant medical capacities that can be used for alternative purposes. This effect is of great importance for the consumers and patients at the collective level. Under the given scarcity conditions and capacity constraints it creates an immediate medical benefit for those patients who do need a doctor. Furthermore, it particularly reduces the costs associated with waiting times for patients who see a doctor.<sup>150</sup>

Notwithstanding these observations, when searching for incentive mechanisms through health policy, which may help to bring switches to success and by this strengthen the self-care sector in Austria, it has to be taken into account that consumers ground their personal judgement and decision on the individual case perspective and not on aspects of public welfare, i.e. an aggregated approach. This dilemma can only be overcome by monetary steering instruments and incentive mechanisms which induce the individual to make his decision in consideration of public interest objectives.

Verbrauchersicht. Frankfurt 2006.

<sup>149</sup> GfK (2017): Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPHA. Wien 2017.

<sup>150</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013

## 5.1.2 Pharmacists and Physicians

It is obvious that the importance of a competent contact person such as the pharmacist for the consumer is particularly high in the area of indications and substances that were previously a medical domain. A first conclusion from this being that the restriction of the dispense of OTC medicines to pharmacies only can be particularly well justified in the light of switches and is therefore also justifiable by health policy. The concern partly expressed by pharmacists that switches would endanger the “pharmacy-only principle” therefore appears unfounded. On the contrary, the mentioned necessity of an increased requirement for advice forms the basis for the political argumentation for maintaining the mandatory dispense of OTC medicines as a whole by pharmacies, so that switches can in this respect be welcomed from a pharmacy perspective. The President of the German Pharmacists’ Association Fritz Becker declares the advice provided in self-medication as the “supreme competency” of pharmacy and concludes: “*OTC switches with tight monitoring by pharmacists offer great opportunities for care*”.<sup>151</sup>

Furthermore, some pharmacists argue that Rx-to-OTC switches could pave the way for migration of the medicines from public pharmacies to other distribution channels. Behind this, among others, is the fear that the pharmacy requirement for OTC medicines could be entirely abolished, leading to previously switched medicines getting somewhat lost for pharmacies. The authors of the present expertise consider this concern not only as unjustified but even wrong and harmful. While there are individual voices from commerce calling for an abolition of the restriction of OTC medicines to pharmacies out of economic interest, such claims are professionally and objectively not acceptable in the light of consumer protection and will therefore consequently find no resonance at political and official level. There are no indications of developments or political movements which could lead to a change of this majorities.

If switches are not undertaken due to an alleged protection of the “pharmacy-only principle”, this is not only unfounded but also counterproductive; especially when, as argued above, challenging and advice-intensive substances or indications become accessible to self-care by switches, thus raising the demand and the necessity for advice, and where required monitoring of the medication. Consequently, the risk of the obligation to pharmacy dispense being abolished would retreat into an even further distance. As a result, pharmacy as the place for dispensing OTC medicines will in this respect be strengthened. This view is supported by a survey of 22 experts, coming from “policy”, “consumer protection”, “market research”, “health professionals” and “science”, on the subject. The respondents expressed unanimously that they consider the pharmacy requirement for OTC medicines as necessary. This applies in par-

<sup>151</sup> Becker, F. (2017): Zukunft von Switches aus Sicht der Apothekerschaft. Vortrag im Rahmen der ersten Switch-Konferenz des BAH am 06.07.2017.

ticular to safety aspects and the quality of self-care, which from the perspective of the respondents depends on the advice and dispense of OTC medicines in pharmacies.<sup>152</sup>

One objection that cannot easily be dismissed is that the Rx-to-OTC switch under the current legal rules in Austria (allowance of mail order for OTC medicines only) creates the prerequisite that a proportion of customers will shift their method of purchase from local pharmacies to the internet and online-purchase. Just over a quarter of the participants in the GfK survey 2017 declared they had bought over-the-counter medicines at least once on the Internet. However, more than half of the respondents stated that their shopping behaviour would not change despite the availability of over-the-counter medicines on the Internet. Incentives for making Internet purchases include above all the lower price (73%), but also the home-delivery (53%) and the local and temporal independence when ordering (43%).<sup>153</sup> However, this challenge is also an opportunity for pharmacists, as switches provide the possibility for them to position themselves in the competition with digital distribution structures as a competent source of advice, including for more complex health issues.<sup>154</sup> Industry insiders also determine reconsideration of this situation and the pursuit of new, visionary paths as crucial for the future of the pharmacist profession.<sup>155</sup>

At the immediate financial level, a switch from Rx to OTC status has no influence on pharmacies because, according to the Austrian margin system for the pricing of medicines, prescription status is not linked to a differentiated remuneration of pharmacies.

The Austrian associations of medical professions have traditionally had a reluctant attitude towards self-medication. The background and reasons for this were analysed in detail and described elsewhere by the authors.<sup>156</sup> Based on the current regulatory situation in Austria, an Rx-to-OTC switch does not imply that the concerned product can no longer be prescribed or reimbursed and by this “gets lost” as a treatment option for the physician. Nevertheless, it

<sup>152</sup> Cf. May, U., Bauer, C. (2017): Apothekengestützte Selbstbehandlung bei leichteren Gesundheitsstörungen – Nutzen und Potenziale aus gesundheitsökonomischer Sicht. In: *Gesundh ökon Qual manag* 2017; 22: S. 12–S. 22. Georg Thieme Verlag KG Stuttgart New York 2017.

<sup>153</sup> Cf. GfK (2017): *Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPHA*. Wien 2017.

<sup>154</sup> Based on aspects of consumer protection and aspects of health economy there are good arguments against the distance-selling of Rx medicines, which can likewise be transferred similarly to OTC medicines. These arguments also apply to a large extent to more difficult and advice-intensive medicines. Cf. May, U., Bauer, C., Dettling, H.-U. (2017): *Versandverbot verschreibungspflichtiger Arzneimittel*. Stuttgart 2017.  
Cf. DAZ online (2017a): Die Preisbindung ist nur mit dem Rx-Versandverbot zu erhalten. Interview mit C. Bauer und U. May. Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/03/28/die-preisbindung-ist-nur-mit-dem-rx-versandverbot-zu-erhalten/chapter:2> (Accessed: 16.11.2017).

<sup>155</sup> As e.g. Ulrich Sommer, Vice Chair of the Apobank in an interview with DAZ online. Cf. Sommer, U. (2017): Apotheker müssen umdenken und brauchen neue Visionen. In: DAZ online. Internet: <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/06/23/apobank-studie/chapter:3> (Accessed: 16.11.2017). In the same sense Cf. further: Oberender, P. (2013): Zukunft der Apotheke, Drei Fragen an Prof. Dr. Dr. h. c. Peter Oberender. In: *Aktueller Wirtschaftsdienst für Apotheker (AWA)*, 38. Jahrg., Nr. 19 vom 1. Oktober 2013, S. 4–5, and Rychlik, R. (2011): Gesundheitszentrum Apotheke. Vortrag bei der Deutschen Apotheker- und Ärztebank (apoBank) in Düs-seldorf am 16.11.2011.

<sup>156</sup> Cf. May, U., Bauer, C. (2013): *Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich*. Wien 2013.

is the aim of every switch to encourage self-medication. This can be regarded as competitive with the therapeutic sovereignty of the physician and as a potential reduction of remuneration-relevant patient numbers. This view explains why not only the relationship to self-medication, but also to non-prescription medicines, can be ambivalent from the physicians' perspective.<sup>157</sup> On the one hand, the physicians appreciate OTC medicines as an important and often well tolerated treatment option.<sup>158</sup> On the other hand, the latest GfK population survey reveals that even in 2017 Austrian doctors have not given recommendations for the self-purchase of over-the-counter medicines very frequently.<sup>159</sup>

The reasons for this opposition may be comprehensible from a medical and professional point of view, but not from the health economic and social perspectives. Various analyses found a distinct connection between the remuneration system for physician services in a national health care system and the attitude of the medical profession towards self-medication and the switch topic.<sup>160</sup> At health care system and policy level, however, there should be a discussion that is elevated beyond such partial interests and works towards a rational and efficient solution from a social perspective. Particularly in the discussion with the medical profession, the need for a strictly evidence-based basis for decision-making in switch procedures has to be once more emphasised.

### 5.1.3 OTC Manufacturers and Rx Manufacturers

The pharmaceutical expenditures in Austria, as well as in other European countries, increase by about 5% per year, resulting in a doubled volume of expenditures within fifteen years.<sup>161</sup> It cannot be expected that the resources available in the solidarity-based health care systems will keep up with this development. The expected pressure on pharmaceutical expenditures due to medical and pharmaceutical progress, and demographic development, will in

<sup>157</sup> Cf. Bardeck, M. A. (2005): *Selbstmedikation und die Rolle des Hausarztes: eine wissenschaftliche Telefonbefragung*. Dissertation zur Erlangung des Doktorgrades der Medizinischen Fakultät der Georg-August-Universität zu Göttingen. Internet: <https://ediss.uni-goettingen.de/bitstream/handle/11858/00-1735-0000-0006-B330-4/bardeck.pdf?sequence=1> (Accessed: 21.03.2016).

Cf. Österreichische Ärztekammer: *Bedenken gegen Forcierung der Selbstmedikation*. Pressemitteilung vom 25.09.2012. Wien 2012.

<sup>158</sup> Cf. IGEPHA (2015): *Die Rolle des Arztes in der Self-care*. In: *QUINTESSENCE Das Medium zum Thema Self-care*. Ausgabe 3/2015.

<sup>159</sup> Cf. GfK (2017): *Selbstmedikation. Eine Studie von GfK im Auftrag von IGEPHA*. Wien 2017.

<sup>160</sup> Cf. e.g.: Gauld, N., Kelly, F., Emmerton, L., Bryant, L., Buetow, S. (2012): Innovations from 'down-under': a focus on prescription to non-prescription medicine reclassification in New Zealand and Australia. In: *Selfcare Journal*. 2012; 3(5): 88–107, Gauld, N. J., Kelly, F. S., Kurosawa, N., Bryant, L. J., Emmerton, L. M., Buetow, S. A. (2014): Widening Consumer Access to Medicines through Switching Medicines to Non-Prescription: A Six Country Comparison. In: *PLOS ONE*. Sept. 2014; 9(9), Gauld, N. J., Bryant, L. J. M., Emmerton, L. M., Kelly, F. S., Kurosawa, N., Bue-tow, S. A. (2015a): Why does increasing public access to medicines differ between developed countries? A qualitative comparison of factors. In: *J Health Serv Res Policy*. 2015; 20(4): 231–9, Gauld, N. J., Kelly, F. S., Emmerton L. M., Buetow, S. A. (2015b): Widening consumer access to medicines: A comparison of prescription to non-prescription medicine switch in Australia and New Zealand. In: *PLOS ONE*. 2015; 10(3): e0119011, Kroth, E. (2017b): Begünstigende und behindernde Faktoren eines Switch. In: *Pharm. Ind.* 79, Nr. 7. S. 927–932 und *OTC bulletin* (1996): UK doctors claim to be comfortable about referring patients to pharmacists. In: *OTC bulletin* Nr. 55 v. 25.01.1996. Solihull 1996. S. 6.

<sup>161</sup> Cf. Michel, M. C. (2017): Sind neue Arzneimittel zu teuer? In: *MMW, Fortschritte der Medizin*. 6 / 159, S. 56–57.

Cf. Pharmig (2016): *Arzneimittel und Gesundheitswesen in Österreich. Daten & Fakten kompakt 2016*. Internet: [http://www.pharmig.at/uploads/Daten\\_und\\_Fakten\\_2016\\_deutsch\\_web\\_15621\\_DE.pdf](http://www.pharmig.at/uploads/Daten_und_Fakten_2016_deutsch_web_15621_DE.pdf) (Accessed: 16.11.2017).



the future significantly increase the pharmapolitical pressure for reforms in Austria as well as at European level. Observation of pharmapolicy in the past suggests that the legislator and health insurance funds regularly react to greater pressure on pharmaceutical expenditures with more restrictive measures, keeping in mind that they are financed by a solidarity-based approach.<sup>162</sup> With this background, a discussion under the heading “Headroom for innovation” aims to discover, whether in addition to the exploitation of potential savings through generics, strengthening of health responsibility with OTC medicines could also help to make better use of the available budgets by financing new innovative medicines.<sup>163</sup> Hence, from an overarching point of view of the pharmaceutical industry, consistent or increasing total sales volumes might be expected, despite reduced expenditures from public health-care for medicines for the treatment of minor health disorders.

It is obvious, that in a very heterogeneous environment of providers, individual pharmaceutical companies may be affected differently by such processes. Notwithstanding the above consideration (“headroom for innovation”), the sales by manufacturers of prescription medicines, provided these medicines are not themselves affected by the switch, will in certain indications *ceteris paribus* be somewhat negatively affected by a switch-induced expansion of self-care. For classical OTC manufacturers who get the chance to incorporate newly switched non-prescription substances/medicines into their portfolio, quite the opposite tends to apply; but here the economic potentials and risks of the specific product and the indication have to be checked case-by-case. From the point of view of this group of companies, OTC switches open up new options that are to be used on a case-by-case basis if the commitment is worthwhile. The numerous companies that are active in both the OTC market and the market of reimbursed Rx medicines have to balance the described aspects.

Of particular interest with a view to switch movements is the perspective of those companies whose products are directly passively affected by a switch (here: substance switch) or who have it actively in their hands to initiate switches for prescription medicines from their portfolio. In the longer term, individual manufacturers will be more or less successful in adapting to the conditions of the self-payer market after implemented switches, so that in the competitive process there will be winners and losers. Whether manufacturers of branded medicines or generic companies belong to the winners in the OTC segment, depends very much on the given regulatory framework. Basically, the self-medication market is nowadays dominated to a larger extent by brands than the prescription business. Efforts already initiated in the prescription market to change the medical prescribing behaviour to more and more active pharmaceutical ingredient prescribing can, depending on the given conditions, also have

<sup>162</sup> Cf. For an analysis of regulatory movements see e.g. May, U., Bauer, C. (2011): Regulierungsinstrumente in der GKV-Arzneimittelversorgung. Eine ordnungspolitische Analyse. Stuttgart 2011.

<sup>163</sup> Cf. E.g. EU-Kommission (2009): Pharmaceutical Sector Inquiry. Final Report. Adoption Date: 8 July 2009. Brüssel. Cf. z. B. IPHA Irish Pharmaceutical Healthcare Association (2012): Pharmaceutical Healthcare Facts and Figures. Dublin 2012.

an impact on the OTC market. In such circumstances however, any economic incentive for an original manufacturer to initiate a costly switch procedure would get lost. As a result, the manufacturers’ perspective is strongly influenced by the given rules for exclusivity and the recommendation behaviour in the pharmacy.

The degree of adaptability and the chances of success on the OTC market after a switch are also expressed in the development of prices in the first few months after a switch. An evaluation of data collected by the market research company Insight Health for various active substances in Germany<sup>164</sup> demonstrates that the prices of Rx medicines, provided they are still available as such after a switch, and the prices the OTC medicines undergo very different developments. They vary from a reduction up to a substantial increase of the sales prices. The following table (Table 7) shows some examples of price trends immediately before (Rx only) and after a switch (Rx and OTC). It is evident that both parallel and contrasting developments in the direction of a price increase and decrease have occurred. Price development is relatively well foreseeable if the newly switched product enters a self-medication environment that has already been established by other active ingredients. From a marketing perspective the new entry regularly has to find its place in the given price structure.

Active pharmaceutical ingredient (API)	Dispensing status	Price one month prior to switch	Price one month after switch	Price three months after switch
Racecadotril	Rx ↑	19.47	19.58	19.77
	OTC ↑	–	5.96	8.85
Esomeprazole	Rx ↑	27.39	27.51	27.62
	OTC ↓	–	11.17	10.78
Ketotifene	Rx ↓	21.67	17.87	17.63
	OTC ↓	–	14.05	13.72
Mometasone	Rx ↓	17.33	17.24	17.24
	OTC ↑	–	10.87	13.86

Table 7: Price development Rx and OTC (in Euro)

The above considerations are also reflected in a member survey conducted by the IGEPHA in early summer 2017. Twelve of the 18 participants were manufacturers of OTC and Rx med-

<sup>164</sup> Cf. Heilhecker, J. (2017): Marktpotentiale von Rx-to-OTC-Switches in Österreich. Eine gesundheitsökonomische Analyse auf Basis eines Mehrländervergleiches. Bachelorarbeit, Hochschule Fresenius, Idstein. (Zur Publikation eingereicht)

icines and six were pure OTC manufacturers. 39% of respondents were of the opinion that there are substances or indications that would get a market relevance in Austria as a result of a switch in the first place. However, only a little less than half of the companies (44%) would currently submit a switch application themselves. The question, whether switches in Austria could develop sales potentials in relevant scope, was answered very clearly (by 94%) in an affirmative way. As reasons for the assumed sales potentials, 88% of the respondents gave the exploitation of completely new revenue potentials, while 35% stated substitution of Rx medicines. The following figure (Figure 27) shows the three most frequently given advantages and disadvantages of switches from the company perspective.

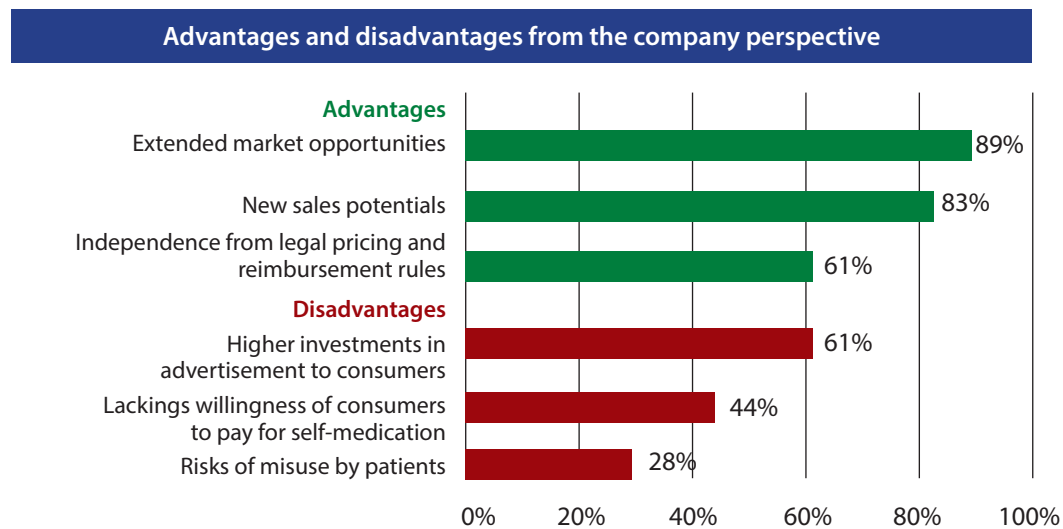


Figure 27: Advantages and disadvantages of a switch from the company perspective<sup>165</sup>

From the figure showing the survey results, it is evident that from the company perspective the advantages seem to distinctly outweigh the disadvantages. Of particular importance in this context are the expansion of marketing opportunities and the opening up of new revenue streams.

In perspective, a future scenario in which the Austrian pharmaceutical market would be more focused on self-medication with the aid of switches, would besides the described challenges offer all manufacturers the chance to develop more freely in a market-dominated environment than in the health insurance market, and finally to act with a higher degree of planning security, detached from the regulatory mechanisms.

<sup>165</sup> IGEPHA (2017b): Mitgliederbefragung: Switches in Österreich. Wien 2017.

## 5.1.4 Health Policy and Health Insurance Companies

The perspective-adjusted analysis of the switch topic for policy and health insurance companies can at this point be performed collectively. Based on the structure and the organisation of the Austrian health care system, the points of view of policy and health insurance, including the Federation of Austrian Social Insurance Institutions, overlap in many areas. This is due to the fact that the Federation assumes statutory tasks with an official mandate and by this takes an overarching perspective, at least for the sectors of social security. Wherever the perspectives of insurance funds and policy differ, this differences will be discussed separately. The role of policy as well as health insurance companies, with a view to the actual act of a switch, is largely restricted to the function of providing the respective framework. Once the regulations and legal provisions are implemented, a direct involvement or intervention by these players is no longer required and, different from patients, pharmacists or manufacturers, they are not e.g. financially affected by the consequences either. It can therefore be concluded that the perspective of policy and insurance funds, in terms of the switch topic, is ultimately determined by the environment resulting from switches with respect to more or less pronounced self-medication in Austria.

The examination of the health economic significance of OTC medicines in Austria, which is relevant in this context, was conducted from a social and overall economic perspective.<sup>166</sup> Naturally, the results of the study are highly relevant for policy, the health insurance companies and the Federation of Austrian Social Insurance Institutions. Basic, factually justified objections to the results of the study, and the conclusions drawn from it, can hardly be expected under scientifically objectifiable aspects.

Ideologically and politically motivated concerns, or concerns based on information deficits, could e.g. go in the direction where a strengthening of personal responsibility could be interpreted as a step towards abandoning the principle of solidarity. Such and other objections from policy and insurance companies can be argued against under economic aspects in connection with the presented study results. It was demonstrated that self-medication can achieve savings for the social health insurance system, which, based on an appropriate design of legal regulations, can be distributed in a way that a better status can be warranted for all, especially socially weaker members of the health insurance. In this process the social component is also accommodated, as through the strengthening of subsidiarity, the financial viability of the Austrian health care system, based at its core on solidarity, can be maintained in the long term.

<sup>166</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.



Self-medication meets the aspect of scarcity of resources in health care, which has to be managed politically, and the associated obligation of cost containment by verifiably saving significant amounts of direct and indirect costs, in particular in the area of the remuneration of physicians and expenditures for medicines. From this point of view, as well as in respect of care-related aspects, policy and health insurances are aligned with each other. With regard to the quality of care and the assurance of the scope of care, self-medication makes important contributions because it reduces the opportunity costs for the use of physicians, meaning that it promotes more efficient use of medical resources for serious diseases.

The health economic analysis has revealed that the contribution of self-medication with registered and non-registered OTC products for the relief of the Austrian health care system is already indispensable today. This means concretely that every euro spent for self-medication in Austria saves an average of approximately five euros in direct costs for the health care system. However, if this form of health responsibility remained entirely unutilised, it would mean additional physician-related expenses amounting to EUR 1.3 billion and around EUR 1 billion of prescription costs for the health insurance companies. The accompanying rush of patients to physician offices is not yet taken into account: this would account for an additional 13 million physician work hours. It can be assumed that such extra efforts by the medical profession and the health care system in the current constitution could not be shouldered.

The market analysis and international comparisons demonstrate that the OTC market in Austria has considerable governing and development potentials. As has been highlighted in the present analysis, Rx-to-OTC switches in particular could contribute significantly to the exploitation of further efficiency and profitability reserves of the described nature. Greater savings for health insurance companies due to a switch-induced increase of self-medication could bring about a significant relief to sickness funds, which would in turn reduce the pressure on insurance contributions and expand the scope of the health insurance funds for important health care services. The relief effect per capita would, with reference to the average of the insured, lie significantly above the individually required spending for OTC medicines. Beyond the mentioned effects, the use of OTC medicines provides medically and economically relevant contributions to the prevention of health disorders, also promoting conscious and self-responsible health management.

The risk that has to be accepted for a proactive defence of switches from the perspective of insurance funds and policy might primarily be connected to the assumption that this would effectively mean a paradigm shift to patient empowerment and self-responsibility. This would partially break with traditional perceptions and, not least, challenge certain positions in the Austrian health system that are aiming to protect their vested interests.

### 5.1.5 Commission on Compulsory Prescription, AGES and other Authorities

(in Cooperation with Dr. Christoph Baumgärtel, AGES, as Co-author)

As decisions on a switch are taken in Austria either by BASG and AGES if it is a single application for a specific product, or by the Commission on Compulsory Prescription in the case of a substance switch which changes the Compulsory Prescription Regulation, the view of these institutions is of relevant importance for the successful conduct of a switch procedure. The Commission on Compulsory Prescription should in particular be included in respective considerations. According to the Compulsory Prescription Act<sup>167</sup> it has been established as an interdisciplinary body and is operated under the chairmanship of a representative from the Ministry of Health and the AGES. The Commission on Compulsory Prescription further comprises members who are entitled to vote from science, the Austrian Chamber of Pharmacists, the Austrian Medical Chamber, social security, the competent authority for medicines, and the pharmaceutical industry. It could therefore create the basis and preconditions for an increase of self-medication with far-reaching switch decisions. Due to the composition of the Commission being based on equal representation and their votes being taken with simple majority decisions, the views which ultimately lead to a decision can be generally complex and heterogeneous.

It is noteworthy that Austria traditionally has a conservative non-prescription pharmaceutical market and that this has been mutually reflected for many years in the decisions of the Commission. That the switch topic in Austria has traditionally been handled more strictly may also in part be due to historical reasons. From the 1960s thalidomide case the national, and at the time correct, conclusion was drawn that the hazard potential can theoretically be lower if a medicinal product is marketed under prescription. At that time thalidomide was under prescription in Austria, but not in Germany. Due to broader access the number of malformations due to Contergan was significantly higher in Germany, not only in absolute, but also in relative terms. However, it must be taken into account that the case was in principle linked more to a failure of market approval because of lacking legal regulations than to the prescription status. This was recently also stressed by the Deputy Chairman of the Commission. He assesses this argumentation as correct from a historical view, but considers it today as no longer sustainable as such.<sup>168</sup> Contergan should not have been on the market with the claimed indication, either with or without prescription. Following the international introduction of stricter requirements for market approval such a case can no longer be expected. Meanwhile, new medicines undergo very strict marketing authorisation processes, which were not common

<sup>167</sup> § 5 (1) Rezeptpflichtgesetz, BGBl. Nr. 413/1972

<sup>168</sup> Cf. Baumgärtel, C. (2017): Switch-Projekt – Position der AGES, IGEPHA News, Ausgabe 2017/03.

at that time. Furthermore, a new medicine is first marketed under prescription for five years, before a switch can be taken into consideration.

The present survey on the switch situation in Europe has for the first time transparently revealed the extent of the tradition regarding over-the-counter medicines in Austria, which has conservatively grown for decades. The Commission on Compulsory Prescription will also be aware of this fact. It could consider in a future-oriented approach whether potential supply gaps in terms of self-medication could be closed for specific indications and by this, based on the above proposed advanced assessment criteria, create an additional added value. As the over-the-counter pharmaceutical market has so far been extremely conservative, it is realistic and conceivable to include consideration of “empowered patients” being granted more responsibility in future assessments. This could further strengthen personal responsibility and health literacy, which will be both prerequisite and consequence of this opening.

In connection with possible switch procedures, a further Commission, the so-called “OTC Commission” is of importance. It is responsible for the mitigation of possible risks due to potential interactions of OTC substances.<sup>169</sup> With the establishment of “e-medication”, all prescription medicines will be electronically recorded prior to their dispense to an individual patient and simultaneously subjected to a check for interactions with all concomitant medication. The theoretical concern emerged from this that, through a switch, certain substances would no longer be included in the individual interaction check.

To avoid this situation and to ensure that interactions triggered by new OTC substances will also be securely covered and detected, those non-prescription substances that can have clinically relevant interactions shall now also be included in the “e-medication” in Austria, which originally had been primarily planned for prescription substances. Now, quite deliberately, those OTC substances that can have clinically relevant interactions are included in the mandatory list of substances which are covered by “e-medication” and checked for interactions. This happens upon recommendation of the OTC Commission which was established for this purpose in 2013. The operation of the OTC Commission further minimises the substance-related and application-related risks of potential OTC switches.

## 5.2 Overall Assessment from the Perspective of Society

From an economic perspective an allocative question is ultimately behind every switch decision: to what extent can an effective and efficient supply of medicines be realised by self-medication instead of the use of ambulatory medical care? The starting point for the evaluation

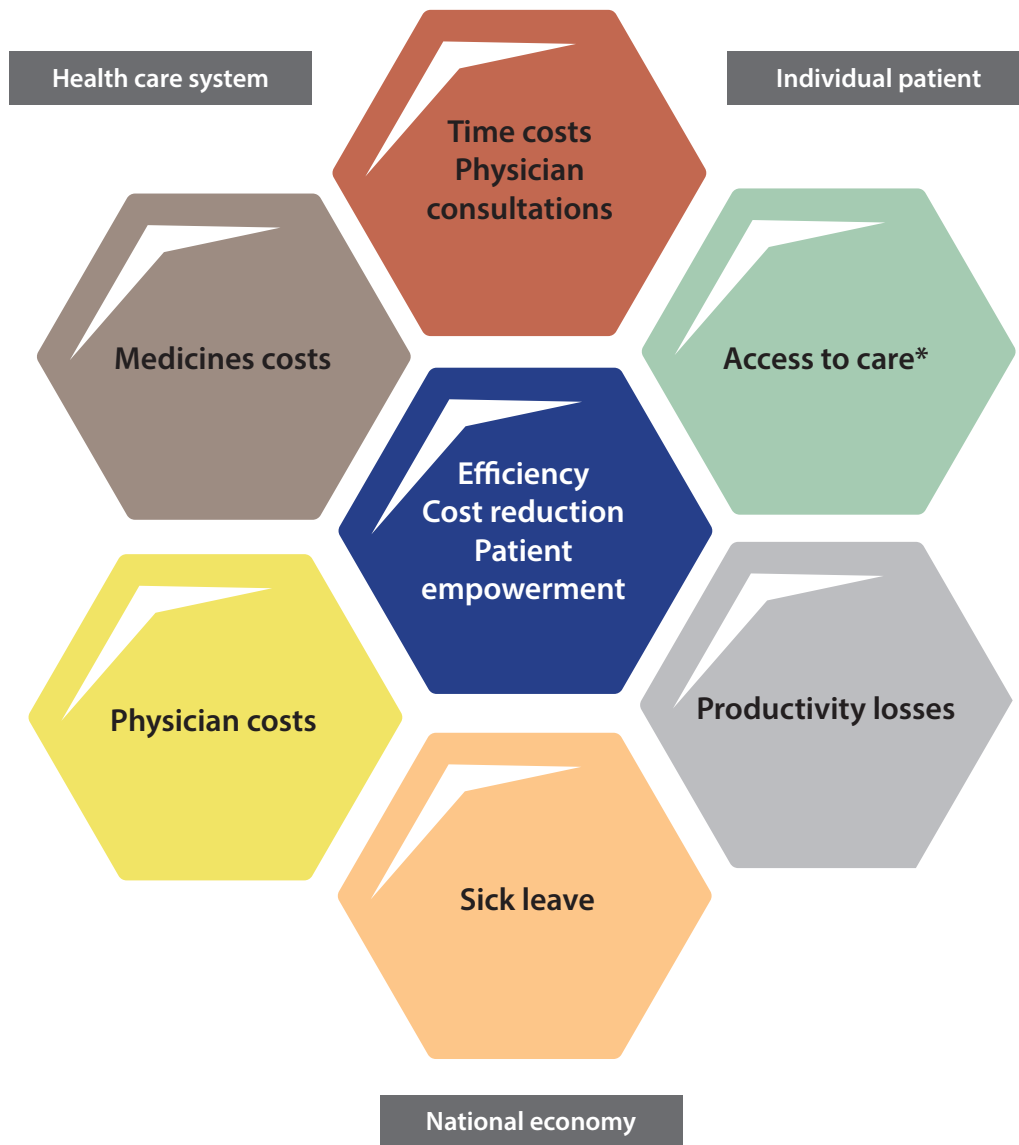
<sup>169</sup> Cf. § 13, Verordnung des Bundesministers für Gesundheit zur Implementierung von ELGA (ELGA-Verordnung – ELGA-VO).

of this question is the social perspective – especially due to the decision of society to ground financing of the public health system on the principle of solidarity. The perspective of society goes beyond the individual perspectives of the groups involved in the supply of medicines. The objectives which can be formulated for the individual sector are bound to an overarching perspective of objectives which can be formulated for health care in total (and eventually the whole economy). Therefore, for the assessment of the fulfilment of single sector objectives, the impact on other sectors of society must be taken into consideration.

In the end there are two central questions: 1 How important is self-care in Austria today and how important will it be in the future? 2 Shall switches concomitantly be promoted or inhibited? For an answer to these questions, from the perspective of society decisive individual importance shall neither be attributed to the vested interests of pharmacists, physicians and pharmaceutical industry nor internal regulatory viewpoints or interests of health insurance. If an individual group might be taken in order to draw conclusions on the perspective of society, it should be the perspective of consumers and patients, which is closest, because at the aggregate level the consumers are not only affected by the benefits, risks and the quality of treatments, but also by the costs of the health care system and economic effects.

Figure 28 brings together the perspectives that are relevant for society and their significant beneficial factors through switches. The reduced consumption of resources by the health care system in the area of medical and pharmaceutical supply, as well as the contribution of self-care to macroeconomic variables such as sick leaves (AU days) and productivity, have already been estimated at a general level in the investigation of the health economic significance of OTC medicines in Austria.<sup>170</sup> With regard to a specific switch project, this data can be used and adapted to the specific situation. Likewise, the patient-relevant effects concerning access to care and e.g. the avoidance of time costs through physician consultations are to be determined for a specific switch case. The decision on the concrete switch case has to be taken on this basis. In this process, and for shaping the framework of self-care, the individual perspectives are only of individual significance insofar as they shed light on the incentive structure of the players. The socially desired effect will ultimately only occur if the objectives and motivation that stimulate pharmacists, doctors, manufacturers and others are incorporated in the framework in a way that they are incentive-compatible for these players.

<sup>170</sup> Cf. May, U., Bauer, C. (2013): Der gesundheitsökonomische Stellenwert von OTC-Präparaten in Österreich. Wien 2013.



\*The improved access to care relates to the relief of burden from general practitioners' offices as well as the low-threshold access to OTC medicines in pharmacies.

Figure 28: Society-relevant effects of switches

The advanced approach to the risk-benefit assessment of switches, considered under the four categories "substance-related", "application-related", "care-related" and "scarcity-related" risks, which was introduced in Chapter 3.2.4 is compatible with the assessment of switches from the perspective of society as it is claimed here and also allows operationalisation of this assessment.

## 6 Gain of Knowledge and Conclusions

Today, self-care already achieves significant positive effects for the relief of the health system, the economy, and for the welfare of patients in Austria. One basic early statement in the present study is that Rx-to-OTC switches are a central incentive for individual health responsibility and self-care, and that with the use of switches the mentioned positive effects can be further expanded. This is even more true for Austria than for many other countries, as substantial gaps in available non-prescription medicines were identified there in the course of the international comparative analysis included in this expertise.

However, a more in-depth analysis of these substance gaps led to the intermediate result that a purely quantitative comparison, based on the number of non-prescription medicines, leads to an overestimation and distorted perception of the problem. In fact, it should be questioned critically to what extent the non-available OTC substances are still important for care or whether they have meanwhile become somewhat medically and pharmaceutically obsolete. In such cases, a switch would be irrelevant from a care perspective and as a catalyst for self-medication, as well as unprofitable in business terms for the manufacturers and from the perspective of the regulatory authorities.

Beyond this group of substances, several switch candidates have meanwhile been identified among internationally widely available non-prescription substances, which are of great interest due to both care-related and economic aspects. A separate algorithm was developed to prioritise such potential switches. In a three-stage procedure a ranking was created based on the weighted criteria risk, relevance for care, and market significance. The cases that have been selected with the aid of these criteria, and been listed in the present investigation, shall be understood as a suggestion to manufacturers, as well as all institutions involved in the switch process, and authorities in Austria, to evaluate the respective applications for switches. A striking phenomenon that has been identified by the international comparative empirical evidence is referred to as the "dilemma of small countries": due to the size of the market a series of interesting substances are not approved or only approved, but not marketed in Austria and other countries of comparable size. In addition, switch applications are less often initiated in smaller countries, obviously not least due to the background of the existing economic potential. From the business perspective, this may be rational in many cases. Therefore, the authors appeal to the authorities and law-makers in Austria to design the conditions of the framework in such a way that there are sufficient incentives for market access and switches in Austria. Harmonisation of the prescription status at European level involves the risk of finding oneself at the "lowest common denominator" and by this stepping backwards. A more pragmatic solution could be a "piggy-back" system, meaning that switches in certain comparable

and therefore appropriate reference countries would be automatically adopted in Austria. The fundamental and central requirement, to shape the data exclusivity for applicants appropriately, both with respect to the requirements for granting it and the duration of the protection period, is not only relevant for the removal of the identified substance gaps but above all with regard to so-called innovative switches.

Whereas in the present analysis the problem of old substances gaps could be relativised, the potentials and opportunities arising from switch projects that are nowadays still considered visionary in Austria are more striking. The analysis carried out for this purpose reveals that Austria has so far not manifested itself in terms of innovative switches or even so-called “first-in-world switches” in the past. At the same time, examples such as Finland and particularly New Zealand show that even small countries can be pioneers in this regard. Innovative switches are characterised by the fact that they go beyond the traditional limitations of self-care on the one hand, but on the other entail specific, positive effects on the practice of care. The latter often involve a patient-relevant benefit, which justifies weighing certain application- or substance-related risks against these benefits.

Particularly motivated and inspired by such innovative switches, but also intended for use in traditional switch projects, a new advanced approach for a risk-benefit assessment of switches has been formulated in the present expertise. This approach is first of all based on the definition of four medical risk categories, comprising so-called care-related and scarcity-related risks, in addition to the usually included substance-related and application-related risks. This expanded concept of risk is integrated into a new decision-theoretical perspective: the current standard for evaluation primarily focuses on the associated risks if a substance X is either dispensed in the context of a medical prescription or via self-medication and compares the results with each other. In contrast, the authors would prefer to undertake the evaluation from the perspective of the patient. The options for action of the patient vary depending on the prescription status of substance X. From his individual benefit calculation, he will take one or the other decision, e.g. in favour of seeing a doctor, self-care or doing nothing. The benefit-related effects and risks that may result from these real-life decisions are the aspects which, based on the proposed approach, should play a significant role in decision making on the prescription status.

From this perspective, projects that at first sight appear visionary partly present as quite realistic and worth being seriously discussed. With this background, among others the switch of anti-asthmatics for long term and acute treatment, the switch of sildenafil, and the OTC status of certain vaccines – in connection with possible vaccinations in the pharmacy – were presented as examples for discussion.

The idea of a new advanced risk-benefit assessment of switch projects is on the one hand addressed to authorities and bodies which must regularly take such decisions. Here discretion can be used in the desired direction and modifications of the regulatory framework be initiated. On the other hand, the proposal is also addressed to pharmaceutical companies, especially if they seek innovative switch projects. According to the motto “new paths emerge when they are gone” the spectrum of data than can be submitted for switch applications could be extended to relevant socio-economic data and considerations. In this way, additional arguments for or against switches are incorporated in the professional opinion-forming.

A further step focused on the question of what factors inhibit or promote the success of switches and the switch climate in a country or a health care system. Empirical results were retrieved from an international comparison on the basis of a literature review. This was followed by an analysis of the situation in Austria in terms of the identified switch-relevant factors. Noteworthy as favourable conditions in Austria include especially the mandatory dispense of OTC medicines in pharmacies and the existing pricing system, as well as the relatively liberal advertising regulations. Furthermore, the openness and constructive dialogue with the BASG and AGES contribute positively to the switch climate in Austria.

However, the list of switch inhibiting factors in Austria is much longer. Of utmost and fundamental significance is the fact that there is no political backing and no active support for the topics “self-care” in general and “switch” in particular in the country. This fact is reflected in various regulatory areas as well as in the mentality and behaviour of patients with regard to individual health responsibility. Current population surveys show that the attitude of Austrians towards self-care approaches is indeed quite positive. It could, however, be much further implemented in practical actions of the individual. Other serious obstacles for switches include the dispense right of physicians and the very restrained to negative attitude of the medical profession towards non-prescription medicines and self-care in general. The “dilemma of small countries” and the lack of incentives for market launches and switches as additional inhibiting factors were already mentioned above. Last but not least, efforts to make the switch procedure in Austria more transparent and efficient shall be expressly welcomed with a view to the results of the present expertise. A positive switch climate also implies that discussions about switches and eventual re-switches are performed with a sense of proportion and with the inclusion of socio-economic aspects.

The special role of pharmacies at the borderline of self-care, i.e. especially in the context of switches, has been substantiated not least on the basis of the results of population surveys. Particularly in connection with innovative switches, the responsibilities of pharmacists could be expanded and represent a great health-economic potential.

In a conclusive part of the study, the perspectives of individual stakeholders in the switch context were evaluated in more detail. The findings concerning the perspectives of consumers and patients, pharmacists and physicians, policy and health insurances, as well as the regulatory perspective, can be helpful to create appropriate conditions in practice that will bring switches to success.

One additional central finding of the perspective-oriented investigation is the following: the significance of self-care and switches in Austria must be discussed from the perspective of society. Neither the competing vested interests of pharmacists, physicians and the pharmaceutical industry, nor the internal views of authorities or health insurance funds, should be assigned inappropriate weight. From the perspective of society, only the perspective of consumers and patients should be assigned a special and decisive weight in terms of the switch issue. Based on these considerations the switch candidates identified in the present study should undergo critical as well as open evaluation.

## 7 Authors



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