From prescription-only to pharmacy-only

The views of Pharmacists, Physicians, Patients on switches.
**Pharmacists**

- **85%** support further switches
- **95%** recognize an increased competency of pharmacists

Top 3 indications:
1. Hay fever
2. Acne
3. Migraine

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**Physicians**

- **51%** support further switches
- **33%** recognize upgrading of physicians concerning serious health problems

Top 3 indications:
1. Hay fever
2. Acne
3. Heartburn

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**Consumers**

- **57%** support further switches because of good advice from pharmacists
- **43%** reckon vaccinations by pharmacists to be reasonable

Top 3 indications:
1. Bladder infection
2. Fungal diseases
3. Migraine

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Dear reader,

Germany will change in the years to come. The key development will be demographic change, shaping the work and living environment of people. The health care system needs to accommodate medical progress and yet remain powerful, affordable and personal. In this scenario, self-medication generates healthy perspectives for the individual and for the whole of society. Today, it has already become a building block for patient-oriented, comprehensive and financeable health care.

More and more people are watching their health, with responsible and health-interested individuals assigning greater importance to the freedom of decision making concerning their own health. This wish complies with the needs of society and an increased personal responsibility of the individual. This development creates the possibility of making health care more individual and more efficient. However, for this purpose the availability of products and services plays an important role. On-site pharmacies in particular will play an increasing role as low-threshold points of contact for advice and as a guarantor of appropriate care. Pharmacies can provide the personal attention to the consumer which is important for therapeutic success and, likewise, offer the reassurance that potential risks, as well as risks in his individual situation, have been competently identified.

Increased self-medication frees up more resources in physicians’ offices for patients who really need a physician consultation. This also has a cost-saving effect for the compulsory health insurance system (GKV). The time spared through the waived physician consultation can be used by the patients for recovery. Currently, 71 percent of the German population already confer on pharmacies a high degree of trustability.

With this background, switches make an important contribution to sustainable health care. This applies to the efficient and needs-oriented care for the individual as well as to the economic perspective of society.

Besides profound health economic calculations, this publication presents comprehensive representative results from surveys of physicians, pharmacists, stakeholders and consumers for the first time. The abundance of facts and views on the topic, which in this form is unique for Germany, shall make an important contribution to the public and political perception and discussion on the topic of switches.

Dr. Traugott Ullrich

BAH Vice-Chair
Way out of compulsory prescription: 
Safety first for every switch

A key characteristic of any medicine is the question of whether it has to be prescribed by a physician or can be dispensed in a pharmacy without prescription as a so-called over the counter (OTC) medicine. However, medicines can also be transferred from prescription to “pharmacy-only” status via a strictly regulated procedure, to the benefit of all. When considering a so-called “switch”, the safety of patients has the highest priority.

Switches as an important element for good quality of care

The experiences that have been gained with switched medicines are absolutely positive. During the past 40 years, 113 active substances have been released from compulsory prescription in Germany. Of these, only three switches were reversed due to newer medical findings which had not previously been known. The most obvious benefits of switches are the following:

- **Benefits for patients:** It is far more convenient for patients to get their medicines right away in a pharmacy, accompanied by professional on-site advice. Time consuming consultations with a physician are not always necessary. The low-threshold access to well-established medicines facilitates a prompter start of treatment, including earlier recovery of patients, and reduces the risk of spreading infections.

- **Deburdening physicians:** Less and less physicians have to care for more and more patients. Particularly in rural regions, the shortage of general practitioners is becoming critical. In light of this, health policy should acknowledge that in cases of minor ailments patients could get advice in pharmacies and initiate self-medication instead of crowding physicians’ offices. For this, an adequate spectrum of switched medicines is deemed essential.

- **Saving resources for the health care system:** If a medicine is exempted from compulsory prescription, it will no longer be financed by health insurance funds. Furthermore, cost-intensive consultation and treatment hours in physician offices become redundant. National economies as a whole also profit from switches: As a consequence of better medical care the working population tends to be more healthy and the number of sick-leave days reduced.

**Safety first**

So the benefits of switches are clear. However, irrespective of these benefits, particularly in Germany, the key prerequisite for a switch from prescription to OTC status is the safety of a medicine. This approach is right. Prior to every switch there must be a critical analysis and discussion of whether the active substance has an acceptable safety profile, in order to justify its use without supervision by a physician. Easy handling by the patient is of equal importance as easy self-diagnosis of his disease. The safety first principle leads to a rather conservative attitude of the German authorities towards switches.

**Switch procedure in Germany**

A switch application is typically submitted to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). They are mostly submitted by the pharmaceutical manufacturer. After validation of the application by the BfArM, the Expert Committee for Prescription, situated at the BfArM, discusses submitted applications at its semi-annual meetings. If the experts support an application, the BfArM files a recommendation to the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG). In the majority of cases the BMG endorses the recommendations of the Expert Committee and drafts a respective ordinance for amendment of the Ordinance on the prescription of medicines (Arzneimittelverschreibungsverordnung, AMVV), which is then transmitted to the Federal Council. A switch can only be implemented with the consent of the Federal Council. Alternatively, the BMG can also modify a recommendation of the Expert Committee or refuse implementation, as happened since several years in the case of the “morning-after-pill.”
Pharmacists play an important role

Switches can only be implemented successfully if they are supported by the pharmacist community. Pharmacists are in close contact with patients. They know their needs and can therefore ideally appraise the demand and acceptance of eventual further switches. The views of pharmacists are likewise important when it comes to an effective support of switches by the pharmaceutical industry, e.g. concerning appropriate pharmaceutical forms or information materials for the patients.

Numerous switch candidates

The spectrum of potential switch candidates is broad, ranging from further nasal presentations of anti-inflammatory glucocorticoids, to the active substance sildenafil for erection problems and to oral contraceptives. For all these active substances, examples of other countries can be given where they have already been switched and can now be dispensed in pharmacies without a medical prescription. The BAH has explored potential future switch candidates from the perspective of pharmacists by a study in cooperation with the University of Applied Sciences Kaiserslautern.

Three important prerequisites for switches

- The active substance must be suitable for self-medication. This includes a low level of toxicity and only few side effects, as well as the absence of relevant interactions with other medicines.
- The pharmaceutical form must be suitable and easy to administer. This applies, for example, more to tablets than to preparations for injection.
- Patients must be capable of recognizing the symptoms of the disease and administering treatment safely without medical supervision.

Overview of the switch procedure

1. Submission of a switch application, normally by a pharmaceutical manufacturer
2. Federal Institute for Drugs and Medical Devices (BfArM) validates the documents in terms of completeness and conclusiveness
3. BfArM puts the application on the agenda of the next meeting of the Expert Committee for Prescription and submits its opinion on the application to the Committee
4. Discussion at the meeting of the Expert Committee
5. Submission of a recommendation on the application to the Federal Ministry of Health (BMG)
6. BMG: Where appropriate, the ministry drafts an ordinance for amendment of the Ordinance on the prescription of medicines (AMVV) for consultation by the stakeholders
7. BMG submits the draft ordinance for amendment of the AMVV to the Federal Council
8. Federal Council discusses the amendment and endorses the ordinance for amendment of the AMVV. Publication in the Federal Law Gazette
Representative surveys:
What are the views of German pharmacists, physicians and consumers on switches?

For several decades the discussion surrounding the benefits and risks of switches has always been a purely expert discussion. Throughout the country a little more than three dozen experts, mainly from the authorities, associations and pharmaceutical manufacturers, have fostered a regular exchange on the topic. The views of pharmacists, physicians or consumers have so far not been further elucidated. This is even more astonishing because the health professions in particular can assess the usefulness of switches from their personal experiences. The BAH has now closed this gap with three comprehensive studies, and by this broken new ground. A comparable dataset is so far not available anywhere else in the world.

Study design of the pharmacist survey
The representative survey prospectively queried the demand for switches via the online tool of the pharmaceutical journal “Deutsche Apotheker Zeitung” (DAZ). It was conducted in September and October 2017. 940 pharmacy staff members participated in the survey; of these 752 were pharmacists and 145 pharmacy technicians (PTA).

Besides basic parameters (age, gender, profession), the questions included a list of proposals for new switch candidates, with options to amend the list as free text as well as a voting on the general preparedness and economic and health professional expectations, with a view to further switches. The results were evaluated by the University of Applied Sciences Kaiserslautern.
Pharmacists: Surprisingly strong consent

A surprising and distinct result of the survey is that the majority of the interviewed pharmacy staff support further switches, with 85 percent of the participants arguing in favour of them.

Such broad acceptance had not been expected beforehand because switches always imply some economic risks for pharmacists: as part of their remuneration pharmacies get a fixed amount of €8.35 for every prescription medicine, whereas in the case of non-prescription medicines the price is variable. This may have a negative impact on income predictability. In addition, it is uncertain whether the patients will request the same amounts of the respective medicine after the switch.

Indications and active substances put to the test

For the first time in the world pharmacists were asked which therapeutic indications and active substances should be transferred from prescription to non-prescription status in the future. High consent scores were obtained particularly for the treatment of allergic disorders, acne, migraine and eye infections. The everyday experiences of pharmacists might have determined these scores. Patients in these indication areas need fast and competent help. Moreover, they have often become acquainted with “their condition” over years. It is striking that for the majority of indications, pharmacy-only OTC medicines are already on the market. This means that pharmacists are placed on familiar ground due to their experiences with giving advice to patients.

In terms of active substances, the pharmacists particularly support further switches of third-generation antihistamines, with a special focus on desloratadine. However, other active substances and indications also achieved scores of considerably more than 50 percent, e.g.:

- For hay fever: Budesonid and triamcinolon as further glucocorticoids for nasal application,
- For heartburn: rabeprazol and lansoprazol as further proton pump inhibitors,
- For conjunctivitis: the antibiotic gentamicin,
- For bladder infection: the antibiotic fosfomycin,
- For asthma attacks: salbutamol.

In contrast to this, pharmacists are sceptical about the switches of statins like simvastatin for lipid disorders, oral contraceptives, PDE-5 inhibitors like sildenafil for erection dysfunction and oral antibiotics for acute urinary tract infections.

Do you support further switches?

Yes, with restrictions 41%
Yes 44%
Rather not 12%
No 3%
The survey also covered the views of pharmacists concerning potential switches of vaccines, in particular influenza vaccines for vaccination in pharmacies, which resulted in an almost equal number of proponents and opponents. Whether this rather neutral assessment can also be ascribed to the fact that such kinds of additional services would currently not be remunerated to pharmacies remains unanswered by the survey.

Switches reinforce the competency of pharmacies

The question of whether an extension of self-medication would be judged more as a reinforcement or weakening of the competency of pharmacists is answered by 95 percent of the respondents in favour of reinforcement. This aspect is more important than ever because there is strong competition from internet pharmacies and shady websites offering OTC mail order services. In some places there is also an intensive price war among closely neighbouring pharmacies. Advice and personal contact are still the key factors for customer loyalty in public pharmacies.

Survey results

Do you judge an extension of self-medication more as a reinforcement or weakening of the competency of pharmacists?

Being consulted about the economic significance of extended self-medication, the majority likewise assumes an economic reinforcement. More than nine of ten participants would not consider eventual additional efforts by switches as an essential problem either. A possible reason for a negative answer could be that pharmacies do not receive a special remuneration for providing advice and additional efforts or for eventual adjustments of their facilities.

Should these indications/active substances be switched from prescription-only to pharmacy-only status?

"Yes" / “Yes, but with restrictions”
Physicians:
Proponents hold the majority

Do you support further switches?

- 28% Yes, with restrictions
- 20% Rather not
- 23% Yes
- 4% No information
- 25% No

Which implications for the patient-physician relationship do you see?

- 33% Upgrading of the physician as contact person for serious, really relevant health problems
- 41% Downgrading of the physician as contact person for general health problems
- 26% No implications

Study design of the physician survey

Similar to the survey of pharmacists, readers of the German Medical Journal (Ärztezeitung) could share their views and expectations regarding the OTC switch topic in December 2017 and January 2018. A total of 540 physicians took this opportunity. In order to get a deeper insight, the physician questionnaire queried general information on the participants such as their medical specialty, age and place of activity, in addition to the proposed active substances and indications. Besides that, they were also asked to assess the impact of further non-prescription medicines on the physician-patient relationship and the supply situation of the patients. The orientation and the extent of this survey are likewise unique worldwide, especially with the corresponding pharmacists survey.

There was a relatively high degree of consent to further switches from prescription to pharmacy-only status, which had not been expected to that extent. 51 percent of the interviewees voted for further switches and are convinced that pharmacists can provide the necessary advice.
The potential of further switches is obvious. Through expanded availability of pharmacy-only, but no longer prescription-only products, patients may contact their pharmacist in the case of minor ailments. Doctors would be disburdened accordingly and could make more targeted and effective appointments for acute and serious cases. This would further encompass an economic relief for the health care system. More switches would also have minor implications for the relationship between the patient and his doctor. Every fourth physician expects that additional switches would have no effect on the special relationship, while every third actually expects an upgrading of the view of the physician as the contact person for serious health problems. Only 41 percent of the physicians expect that their importance as a point of contact for general health problems could be diminished with additional switches.

It also contributes positively to the theory that switches and self-medication have a relieving effect on the health care system. And, more than half of the physicians see an advantage for the supply situation of the patients through an expansion of pharmacy-based self-medication.

Switch candidates: Broad agreement with pharmacists

Physicians and pharmacists broadly share the same assessment as to the question of which indications and active substances could be eligible for further switches. Both groups of health care professionals put medications for hay fever and acne in the first two places. Likewise, substances from groups in which other substances have already been switched show the same preferences in both respondent groups. A similar picture emerges for the mostly negatively assessed candidates such as the statins.

Survey results

Can these indications/active substances be switched from prescription-only to pharmacy-only status?

- Hay fever: 64%
- Acne (topical preparations): 63%
- Heartburn: 58%
- Oral herpes: 52%
- Contraceptives: 48%
- Migraine: 48%
- Rosacea: 47%
- Nasal corticoids: 46%
- Erectile dysfunction: 44%
- Eye infections: 39%
- Acute dyspnoea: 35%
- Urinary incontinence: 30%
- Adrenaline injections: 29%
- Stains: 29%
- Vaccines (in part. influenza): 28%
- Urinary tract infections: 22%

“Yes” / “Yes, but with restrictions”
Consumers: Basically positive attitude

Study design of the consumer survey
Within the framework of the representative BAH Health Monitor, at the end of 2017 the market research company Nielsen conducted a Germany-wide consumer survey of 1,000 persons from 15 years of age on the topic of switches. The survey was focussed on the views of switches in connection with quality aspects of pharmacists. Furthermore, there was an exploration of which health problems the participants were suffering from and how they assess switches in the respective indications. The type and scope of the survey are unique worldwide.

In addition to pharmacists and physicians, the BAH has also collected the views of consumers. At the end of 2017, 1,000 Germans from all over the country were interviewed on the subject of switches. The survey was focussed on the views of switches in connection with quality aspects of pharmacists. Furthermore, there was an exploration of which health problems the participants were suffering from and how they assess switches in the respective indications. The type and scope of the survey are unique worldwide.

What is your view on switches?
“From time to time prescription-only medicines which have been available for a longer period and possess a distinctly positive benefit to risk ratio, i.e. which have a low level of side effects, are exempted from the prescription requirement. After this they are available in pharmacies without a prescription, i.e. without consulting a doctor. What is your view on this?”

“This is a good thing because I get reliable advice from the pharmacist.”

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57%

“I look at this positively because I can even better co-decide which medicine is the right one for me.”

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55%

“This is a good thing because I can save the time for going to the doctor.”

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51%
**Indications:**

*Switch demand confirms the assessments of pharmacists*

Similar to the surveys of pharmacists and physicians, there was an investigation as to which indications the consumers would desire switches for. In order to obtain conclusive results, they were interviewed in a targeted manner for their personal health problems. By this, they could answer as “experts”. Interestingly, patients suffering from migraine and hay fever, which also belong to the top 3 switch indications from the perspective of pharmacists and physicians, disproportionately often desire further non-prescription options. With figures of 26 percent and 19 percent, both indications are likewise the most commonly named health problems. Hence, every fourth or fifth of the respondents suffered from these disorders. The particular wish for more medicines for migraine underlines the urgent need for a greater variety of products – although in this area numerous medicines are already available without prescription. With good reason: Migraine patients must often try two or three modern triptan medicines before they experience alleviation. Even their doctor cannot relieve them from this trial-and-error approach.

Of outstanding importance from the patient perspective are also more non-prescription medicines for bladder infections. This should not be surprising, given the intensity of pain and the necessity of rapid treatment. Pharmacists are, however, significantly more cautious in this indication.

**For which indications do the consumers desire more non-prescription medicines?**

“For which of the given health problems are you suffering from would you desire a greater choice of non-prescription medicines available in pharmacies?”

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<th>Which health problems are you suffering from?</th>
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<td>Migraine or headache</td>
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<td>Hay fever or another allergy</td>
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<td>Muscle pain</td>
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<td>Elevated blood lipids</td>
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<td>Fungal diseases, e.g. nail fungus or athlete’s foot</td>
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<td>Bladder infection</td>
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Vaccination switches:
Clear consent

The consumers were also interviewed for their view on potential vaccination switches. Here the Germans are divided in their opinions: 43 percent argue in favour of such switches, whereas 46 percent have another opinion. The attitude of pharmacists towards the topic is similarly ambivalent. The view of physicians, however, looks different: Only about 30 percent argue in favour of switches, whereas about 70 percent of the respondents are against them.

The supporters of vaccinations in pharmacies trust the pharmacy personnel and perceive the switch as a considerable time saving. But they also find it important that the vaccinations should be available to them at a low or even no cost. Independent from the relevance for the individual, 53 percent of the respondents are of the opinion that contraceptive pills should be available in pharmacies without a prescription.

Important contribution to the debate

The results presented here are in this form unique worldwide. Never before have the views of pharmacists, physicians and consumers on the topic of switches been elucidated in an even roughly intense manner. The broad consent to further switches underlines the distinct demand for better care.

What do vaccinations in pharmacies without a prescription mean for the consumers??
Basis: Respondents supporting vaccinations by pharmacists (427 of 1,000)

“German pharmacies have provided advice on vaccinations for some time. Assuming that vaccinations would also be possible in pharmacies without a prescription in the future, what would this mean for you personally?”

“I trust in pharmacy personnel with a specific education for vaccinations.”

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80%

“I see it as a considerable time saving.”

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79%

“I would find it important that the vaccination in pharmacies is free of charge or connected with only low costs (up to 5 Euro).”

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79%
Switches in Germany: New impetus required

For decades Germany has been one of the most liberal nations in terms of switches. Again and again in the past switch projects were initiated for the first time in Germany and afterwards extended to other countries. However, for several years the number of switches of active substances from prescription-only to pharmacy-only status has been declining, as in many parts of the world. Politicians, authorities and the health care industry should now regain more ambition in terms of switches.

Modern switches in focus

German consumers nowadays benefit from the fact that in an international comparison Germany has been one of the forerunners of switches. This can be substantiated by an analysis of important newer active substances and groups of active substances which have been made available for self-medication, such as the triptans for migraine therapy and the proton pump inhibitors for the treatment of heartburn and acid reflux; 62 of these active substances have been switched in Germany in the past. Therefore, Germany is almost neck-and-neck with Sweden at the top of Europe.

In the United States, only about two thirds of these modern active substances have been switched. Worldwide, New Zealand is at the top. Concerning more modern substances for self-medication, Germany is among the leaders – still.

Availability of non-prescription OTC active substances in important indication areas

- Migraine
- Digestive disorders
- Fungal infections
- Pain
- Common cold

Source: AESGP Database, own evaluation
Declining numbers of switches

While the German authorities and the important Expert Committee for Prescription remain generally open to switches, the number of switches in Germany is clearly declining. Some countries have recently been more dynamic in this regard, above all New Zealand. Particularly striking in this country is the very successful dialogue between all stakeholders of the health system, from policy via the health professionals up to the industry. This approach could also bestow a revival on German switch processes.

Switches are essential for the widening of self-medication also for new indications and to deepen it through additional medications for established indications. This can fill therapeutic gaps in patient care and enable patients to benefit from medical progress. Public and private payers can save significant resources with switches, and a responsible expansion of self-medication leaves more time to physicians for patients with serious problems. Compelling reasons for a switch-friendly design of the framework conditions in Germany.

Further increasing demand for OTC products

In 2017 the sales volume of over-the-counter (OTC) medicines in German pharmacies amounted to a value of € 6.7 billion. This corresponds to a share of 12.5 percent of the entire German pharmaceutical market. The importance of the OTC market becomes even clearer when comparing the number of packages instead of the value. With 739 million packs dispensed in pharmacies in 2017, OTC medicines accounted for over 50 percent of the total volume of medicines packages. These figures underline the considerable acceptance of OTC products by patients as well as the demand for self-medication.

Germany as a forerunner for migraine switches

Particular international attention was attracted with the switch of the two triptans naratriptan (2006) and almotriptan (2009) for the treatment of migraine. Both were first exempted from compulsory prescription in Germany. Applications for switches of sumatriptan (oral, 2009, and nasal, 2012) and zolmitriptan (nasal, 2012) were also supported by the Expert Committee for Prescription in Germany. However, the Federal Council rejected an amendment of the Ordinance on the prescription of medicines. The reasons were mainly of a formal nature. A range of four OTC triptans in several pharmaceutical forms for migraine treatment would be unique in the world and mean a real gain of quality of life for patients.
Switch potential:
The health and socio-economic perspective

Visits to the doctor are somewhat associated with longer travel and waiting times, circumstances which represent serious obstacles for patients with certain indications, for example a migraine attack. A visit to the doctor not taking place results in insufficient treatment. On behalf of the BAH, the political scientist Cosima Bauer and the health economist Prof. Dr. Uwe May have examined, on the basis of two indications, to what extent switches can help in such situations.

In our examination we have focused on two potential switches, one of these in the area of the seasonal influenza vaccination. This vaccination switch would be a highly innovative step for Germany, because in our country vaccinations must currently be administered by physicians. Secondly, we have examined the area of bacterial conjunctivitis which would more follow the tradition of previous re-classifications from prescription-only to pharmacy-only status. The innovative aspect would be that the active substance in question would be an antibiotic. Besides the established criteria of benefit-to-risk analysis we have also taken health economic and socio-economic effects into account.

Greater influenza protection through vaccination switch: innovation is overdue

Frequently discussed risks of self-medication play virtually no role for influenza vaccines: the incidence of adverse reactions to vaccines is extremely low, and since the administration of the vaccination would be exclusively restricted to pharmacies, misuse by the patients would be excluded. At the same time, an increased vaccination rate is regarded as an indisputable objective from the viewpoint of medicine and health policy. There are no valid grounds for assuming additional switch-related risks, even after critical analysis.

In addition, there are clear arguments for the vaccination switch from a health economic perspective. An elevated vaccination rate significantly reduces the economic costs due to influenza infections. The positive effects on morbidity and mortality for the population, and the increase in health and quality of life for individuals who do not fall ill because of the vaccination, allows the moderately
increased expenditure of the statutory health insurance (GKV) for vaccinations appear to be appropriate, necessary and economical.

A look into other European countries, where vaccination switches have already been performed, naturally leads to the expectation that this step will also influence the vaccination rate in Germany positively. At the same time, it would be important - and absolutely justifiable with a view to the external positive effects - that vaccinations in pharmacies would be reimbursed by the statutory health insurance, as they are when administered in a physicians’ office.

Conjunctivitis switch: comprehensive benefit-to-risk analysis necessary

From a medical perspective the options for the treatment of symptoms, as they appear in bacterial conjunctivitis, without prior medical diagnosis are partly assessed critically. A layperson can only to a limited extent distinguish them from other eye diseases. Furthermore, there is a danger of possible resistance development. These may be immediate risks.

If the view is expanded to include supply aspects and socio-economic effects, a potential conjunctivitis switch will be evaluated in a more differentiated way. Firstly, a conducted health economic model calculation shows a significant unburdening of the system of outpatient medical care and the resources of statutory health insurance. As a result, medical risks in other areas of care – which are for example caused by an overload of the system - can be reduced. Secondly, according to the representative survey every third affected patient wants more non-prescription treatment options. Thus a switch can significantly increase the quality of care. Positive effects: the patients recover more quickly, they can take up their daily activities and work earlier, and the risk of infection spreading declines.

In order to address the aforementioned concerns, the over-the-counter dispensing of antibiotics in the pharmacy could be linked to certain conditions. For example, it would be conceivable to stipulate that specific personal advice be provided by the pharmacy staff.

Impact of a switch for influenza vaccination

May and Bauer have examined three different scenarios for the impact of vaccination switches. Here: Scenario 2, in a medium term the vaccination rate is increased from 25 to 37 percent.

| 9,920,000 | more vaccinated persons |
| 905,000 | less sick persons |
| 18,700 | avoided hospital days |
| 41 | avoided cases of death |
Discussion and conclusions

The recommendation regarding influenza vaccinations being provided without a prescription in pharmacies is clearly positive. A relevant increase in the vaccination rate can be especially expected if this measure is actively accompanied by targeted information and counselling services in pharmacies. Last but not least, from a regulatory standpoint the vaccination switch can also be classified as a market- and empowered consumer-oriented alternative to the mandatory vaccinations which have been introduced in some neighbouring European countries.

Powerful socio-economic grounds speak in favour of switches in the area of conjunctivitis. Critical objections can for the moment not be rebutted completely. However, these objections must be assessed as secondary in comparison with the benefits of switches.

A follow-up project studying the switch of further triptans for migraine treatment has already started and is expected to show important switch effects at the level of care and, last but not least, with a view to economic costs. The switch discussion will probably pick up more speed.

Impact of a switch in the area of conjunctivitis

May and Bauer have examined three different scenarios for the impact of a switch in the area of conjunctivitis.

Here: Scenario 2, the cases of conjunctivitis treated by physicians decrease by 30 percent.

Costs

Direct

Medicines costs OTC

€ 11,343,000

Savings

Direct

Medicines costs prescription

€ 18,471,000

Treatment costs physician

€ 36,892,000

Indirect

Therapy-related absence from work

€ 7,573,000

Disability-related absence from work

€ 9,749,000

Time of patients

100,428,000 minutes
Looking abroad: Comparison of key switch factors

When it comes to the topic of switches, international comparisons reveal the promoting and inhibitory factors. Essential studies in this regard come from Dr. Natalie Gauld. Among other activities, from 2004 to 2009 she was a member of the Medicines Classification Committee of New Zealand – the country that according to unanimous expert opinion currently occupies the leadership in switches.

Although New Zealand, with a population of just 4.6 million, is much smaller than Germany, elements of the health system are comparable. Unlike Germany, many non-prescription medicines are refunded by statutory health insurance. Medicines are classified into four categories: prescription-only, pharmacist-only, pharmacy-only and products which may be sold outside pharmacies. Hospital care and specialist visits in the public system are free, the family doctor is subsidised, and New Zealanders must pay at most a symbolic fee for prescribed medicines.

New Zealand as pioneer

Despite this situation, for the last two decades New Zealand has become the most progressive country in terms of switches. In contrast to Germany, at present antibiotic medicines for the treatment of eye and urinary tract infections, products for the treatment of psoriasis, an antiviral medicine used to treat the flu as well as a variety of vaccines, including those against influenza, meningococcal disease and cholera, whooping cough (pertussis) and shingles (herpes zoster) are available from specifically qualified pharmacists. In many cases, New Zealand was the switch pioneer. For example, the country implemented the first-in-world switch of sildenafil (Viagra) in 2014. This is amazing, especially since New Zealand is less interesting for global pharmaceutical companies in terms of switches due to the small size of the market.

What are the main factors involved in this pioneering role? Dr. Gauld refers in particular to a pragmatic mentality in New Zealand. The committee and medicines regulator have taken a flexible approach to considering switches. According to certain regulations, switches are simply implemented earlier. Larger health systems are less flexible. Another key to successful switches is the engagement of the pharmacists, says the expert. They have embraced the opportunity to become up-skilled, and have played an important role in aiding access to medicines for people in their community, and relieving pressure from the health system. They undertake extensive consultations with the patients and refer people to the doctor if they need a medical consultation. The Pharmaceutical Society, and other organisations have provided training. Pharmacists in New Zealand are also allowed to charge a fee for dispensing over-the-counter medicines, which makes innovative switches attractive from the perspective of pharmacists.
**Analysis of Germany as a switch site**

On behalf of the BAH, Dr. Gauld has analysed and assessed the situation in Germany, with the support of Prof. Dr. Karl Broich, President of the German Federal Institute for Drugs and Medical devices (BfArM) as honorary scientific advisor of her study.

Result: on the one hand Germany has many switch promoting factors. Among these is the culture of self-medication. The large market is attractive for pharmaceutical manufacturers and the competent authorities provide an opportunity for feedback to industry before a switch. On the other hand, there are also less favourable aspects. For example, there is a lack of political support for further switches. A further point of criticism is the lack of market exclusivity after a switch. Other countries are better positioned in this regard, with the United States and Japan granting a three-year period of market exclusivity to the initiator of a switch under certain conditions. The European pharmaceutical legislation is more restrictive and foresees only the possibility of a one-year protection period, which so far has hardly ever been granted.

As a result of her talks with stakeholders, Dr. Natalie Gauld has formulated a number of recommendations, ranging from proposals for the simplification and acceleration of the switch procedure, via the development of training materials for community pharmacists, up to a legislative initiative for extended data exclusivity for the initiator of a switch.

**Overview of switch influencing factors**

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<th>Promoting factors</th>
<th>Impending factors</th>
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<td>Culture of self medication</td>
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<td>Population and market size</td>
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<td>Involvement of pharmaceutical industry</td>
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<td>Cooperation with competent authorities</td>
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<td>Engagement of individual persons</td>
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<td>Confidence of industry in the switch committee</td>
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<td>Support by pharmacist associations</td>
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<td>Support by policy</td>
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<td>Market exclusivity and transparency</td>
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<td>Support by physician associations</td>
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<td>Refusal of changes</td>
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* No Data
Framework conditions: Offering dialogue and competitive equity

In 2018, for the first time in a long time, a meeting of the German Expert Committee for Prescription was cancelled because no pharmaceutical company had submitted an application for a switch. In addition, the implementation of the recommendations of the Expert Committee have been delayed repeatedly and latterly took more than twelve months. The switch pipeline is threatening to dry up. This is particularly concerning as switches offer concrete answers to the challenges of demographic change, the intensifying shortage of physicians and the limited resources in the health care system. Moreover, they allow better care for patients. From the perspective of the BAH, it is necessary to adjust the applicable framework conditions.

Switches: also a business-related question

Pharmaceutical manufacturers are commercial enterprises which must closely consider whether and, if so, in which country they seek the reclassification of an active substance or a medicine from the prescription-only to the pharmacy-only status. The effort is significant: for a promising switch an abundance of information must be compiled and evaluated by experts. In some cases, additional time-and-cost-consuming studies are required.

Intensifying the dialogue

After an application has been submitted, the switch procedure is performed without involvement of the respective companies. The switch is first evaluated by the competent federal authority and the Expert Committee for Prescription. If the committee issues a positive recommendation, the Federal Ministry of Health can endorse this recommendation and forward a corresponding draft implementation ordinance to the German Federal Council for approval. After a favourable vote from the Federal Council the active substance or the medicine can finally be marketed without a prescription.

This approach has proven itself in principle, but it requires a long wait for the companies. Therefore, it is all the more important to shape the process as efficiently as possible for mutual benefit. However, at present the applicant companies neither receive the assessment of the competent authority nor are they involved in the discussion by the Expert Committee. Such an approach is deemed outdated. Therefore, of particular importance are the so-called scientific advice conversations, in which the companies can discuss essential aspects with the competent authority ahead of their submission of an application. By this, mutual misunderstandings can be resolved and expectations clarified. This form of expert dialogue must be extended.

Expanding market exclusivity

The second major problem is the lack of market exclusivity. It takes at best nine months from the submission of an application until the implementation of a switch, but frequently significantly longer. As the discussion points of the Expert Committee for Prescription are published, potential competitors have plenty of time to develop their own products for the OTC market, without having invested even one euro in the burdensome application procedure themselves. If the switch is successful, products of competitors can likewise enter the market under the same conditions from the first day of implementation. This missing market exclusivity makes switch applications unattractive for many companies. In theory, both the European and German drug laws provide the possibility of a one-year protection period for companies who have substantiated their switch with “significant preclinical or clinical studies”. But such protection has so far been granted only once in Germany,
and it was redundant due to a simultaneously existing patent protection period. In any case, according to the unanimous conviction of experts a one-year protection period is much too short to recoup the expenditure from a switch application.

Other countries such as the United States and Japan have recognized the importance of an extended period of market exclusivity as an incentive for switch initiators. They grant their companies a three-year protection period subject to submitted documents, provided that they were important for the switch application. The German legislator should respectively adapt the local rules.

Another alternative would be a release from the prescription requirement based on medicinal products instead of active substances. By doing so, switch initiators would also be given an edge over their competitors, because their products would be switched quasi-exclusively. Some EU countries, unfortunately including Germany, don’t offer this option. The procedures, for example, in Austria, Greece and Portugal could serve as a model: in these countries the initiator of a switch can decide for himself whether he requests the switch for a specific medicinal product or an active substance. Most of the other countries of the EU enable only medicine-specific switches.

Switches for medicinal products or active substances?
A determinant of market exclusivity!

- **Market exclusivity and flexibility are enabled:**
  Freedom of choice – companies can decide whether they apply for a switch of a medicinal product or an active substance.

- **Market exclusivity enabled:**
  Companies can only apply for switches of medicinal products.

- **Market exclusivity not enabled:**
  Companies can only apply for switches of active substances – possible profit for competitor countries.

- **Other countries:** No information

The BAH and its members support all activities that may help Germany to resume its pioneering role in the area of switching. The focus should now be placed on the creation of appropriate framework conditions. It would be well worth the effort.