



Self-care and self-medication as central components of healthcare in Germany – on the way to evidence-based pharmacy[☆]



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ABSTRACT

In Germany, self-care is, above all interpreted as the prevention and treatment of minor injuries and illnesses by the patients themselves – that is, without a physician's prescription or medical advice. Maintaining one's health in the sense of a preventive approach through non-medicinal measures also plays an important role. Self-medication in this context is the treatment with approved over-the-counter-(OTC)-medications. In addition, other OTC-products such as dietary supplements as well as complementary and alternative medicines including homeopathic medications are frequently requested options by pharmacy customers. OTC-medications are central components of the German healthcare system, with expert advice from pharmacists in community pharmacies (CP) enabling safe and effective treatment. Additionally, screening for appropriate self-medication by pharmacists ensures that serious illnesses receive timely medical attention.

In addition to prescribed medication, self-medication is an important part of the CP business in Germany. In contrast to prescription products, the price of OTC-products is not regulated. As a consequence, the price of OTC-products (including also pharmacy-only drugs) is influenced by competition among CPs and mail-order pharmacies, respectively. The sales of OTC-products for self-medication outside pharmacies, e.g. in drugstores and supermarkets, is restricted to a limited number of specific products.

Evidence-based counseling in CPs, while generally advocated still remains a challenge. The evidence for the usage of OTC-products from clinical studies is not yet optimally integrated into everyday pharmacy practice. Information tools such as EVnews offering regular newsletters and a database have been developed to reduce the evidence-to-practice gap and to improve the overall counseling quality. Furthermore, the switching of drugs from prescription-only to pharmacy-only status also challenge CPs to provide adequate and updated guidance.

1. Self-care

The aim of self-care is to maintain or restore health or to prevent serious illnesses.¹ The term self-care often embraces self-medication and appropriate use of medicines, dietary supplements, and other health products, which may also include recommending health-promoting measures such as increasing physical activity. The World Health Organization (WHO) broadly defines self-care as the ability of individuals, families, and social groups to promote health, prevent disease, maintain health, and manage illness and disability with or without the assistance of a health care provider.^{2,3} No government and/or professional

association health reports could be located for Germany that gave equal consideration to self-care or referenced the WHO's seven pillars of self-care. Of note: there is no meaningful translation of the term self-care in this sense into German.

Compared to international activities of self-care,⁴ definitive activities in German community pharmacies (CP) have been focused, above all, on self-medication. There are some post-graduate specialization options for pharmacists, addressing self-care activities, especially in the field of CP for nutritional counseling, prevention, and health promotion.⁵ Self-help organizations have also been frequently considered to make an important contribution to patient-centered care.⁶

Abbreviations: ADR, adverse drug reactions; AE, adverse events; CP, community pharmacies; DRP, drug-related problems; OTC, over-the-counter; PHI, Private Health Insurance; SHI, Statutory Health Insurance.

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There are CP activities in self-care, for example, in the field of smoking cessation. CPs offer services to smokers in the prevention of smoking-associated conditions such as chronic obstructive pulmonary disease, lung cancer, peripheral artery or coronary heart disease as well as part of rehabilitation e.g., post-myocardial infarction.⁷

For the over-the-counter (OTC)-sale of emergency contraceptives (“morning-after pill”), evidence-based recommendations are available from the German Federal Chamber of Pharmacists.⁸ In these recommendations, the requirements for the appropriate and safe use of levonorgestrel and ulipristal acetate for emergency contraception in self-care are described including the inclusion of a check-list.⁸

A more recent development is the vaccination of patients in CPs.⁹ In addition to COVID-19, influenza vaccinations are also offered. Based on new legal regulations, contractual and professional requirements have been developed by pharmacy associations. However, the vaccination service is not being offered by all CPs. According to a representative survey conducted by the ABDA – Federal Union of German Associations of Pharmacists Association in late summer 2022,⁹ at least one third of all CP owners wanted to offer influenza vaccination. By the spring of the same year, more than 7000 pharmacists had been trained. The uncomplicated and easy accessibility of services in CPs is intended to motivate additional population groups to get vaccinated. Influenza vaccination is recommended for people over 60 years of age, people with underlying chronic diseases, pregnant women, children with chronic respiratory diseases, and professions with an increased risk of contact.⁹ In Germany, 47% of the persons over 60 years of age have been vaccinated for influenza which is far below the recommended rate by the European Union of 75% in this age group.¹⁰

2. Self-medication

Self-medication is a part of self-care and is defined as the independent use of medication, usually OTC-products, by the patient. OTC-products are medications that are sold directly to the patient without a prescription.¹¹ In Germany, self-medications include both pharmacy-only products as well as products that are available in supermarkets and drug stores (according to the General Sales List). Differently from this definition of OTC-drugs by *Barrenberg et al.*¹² others also include “dietary supplements such as vitamins or minerals”, approved medicinal products, and functional foods as self-medication.¹³

3. German healthcare system

In 2022, Germany had a population of approximately 84 million inhabitants with the proportion of older people increasing.¹⁴ About 10% of the gross domestic product is currently spent on healthcare.¹⁵ A Statutory Health Insurance (SHI) system consisting of approximately 100 insurance funds has been established back in 1883 in the context of the Social Security System by *Bismarck*. A total of 88% of the German population are insured through the mandatory SHI.¹³ Those who are not subject to the SHI obligation, except for example employees above a minimum income, civil servants, and self-employed persons, can take out Private Health Insurance (PHI).

4. Community pharmacies (CP)

In 2022, there were approximately 53,000 pharmacists, 74% of whom are females, who work in approximately 18,200 CPs.¹¹ It is mandatory by law, that German CPs are owned and operated by a pharmacist.¹⁶ Pharmacists may own up to three subsidiaries in addition to their main CP. Pharmacists' activities consist primarily in the dispensing of prescribed medications, counseling patients with regards to medication therapy and safety, OTC sales, and providing lifestyle and healthy living advice as well as compounding medicines.¹⁵ Since June 2022, five professional pharmacy services are reimbursed by all health insurance funds/companies i.e., SHI and PHI.¹⁷

Although patients in Germany are free to obtain medication from different CPs, nine out of ten patients who regularly take three or more medications decide to obtain all their medications from a single CP.^{1,11} Many patients use OTC and prescribed medications simultaneously: For one tenth of all patients with polymedication (defined as long-term use of five or more medications), OTC-products are part of their medication regime.

The customer generally bears the costs of OTC-medicines as, since 2004, these are no longer funded by SHI funds. Exceptions comprise children under 12 and adolescents with developmental disabilities up to 18 years of age. Furthermore, non-prescription pharmacy-only drugs can be reimbursed for adult patients for some defined indications.¹⁸ A list outlines those which are explicitly regulated.¹⁹

5. Self-medication data

In 2021, self-medication accounted for EUR 3.45 billion sales² that is 5.7% of the annual CP turnover.¹¹ In 2021, 436 million packages were sold in the self-medication sector in CPs.¹¹ The 7-day prevalence of OTC-drug use in Germany was 52.0% in women and 40.8% in men.²⁰

The number of OTC-packages sold in CPs is steadily decreasing since patients increasingly use mail-order pharmacies: In 2019 and 2020, 497 and 447 million packages were sold in CP.¹¹ Nevertheless, nearly half of the total of 1.4 billion medications dispensed or sold in CPs each year are OTC-medications. OTC-medications account for around half of all packages dispensed by CPs during night and emergency services.¹ Every year, around 400 million health problems are addressed by self-medication - usually with the help of a CP - so that expenditure by SHI and PHI on medications and unnecessary physician or emergency visits are avoided. According to model calculations, this will relieve the burden on the healthcare system by more than EUR 20 billion annually, mostly in medical follow up costs and productivity losses. In view of the high number of visits to physicians in Germany by international comparison and the increasing shortage of physicians, self-medication continues to play an increasingly important role in healthcare policy.¹

6. Preventing risks in self-medication

OTC-products can pose risks for adverse effects, misuse, and other drug-related problems (DRP), particularly when used inappropriately without an in-depth counseling at the CP. Examples of an inappropriate use include exceeding the recommended dosage or intake duration without seeking medical advice. There is evidence to suggest that between 10% to 12% of OTC-products sold in Germany are reported to have a potential for misuse.¹¹ One fifth of all potential drug risks reported by CPs to the Drug Commission of German Pharmacists concern OTC-products.¹¹ The fact that low-risk OTC-products are frequently involved in Medication safety notifications to the drug commissions underscores the need for counseling also of this drug group in the CP. This is the case because counseling can minimize risks or identify risk factors in time and prevent inappropriate therapies. In,²¹ a total of 12,567 encounters between pharmacist and customer involving self-medication were studied with DRPs identified in 17.6% of the cases. In,²² drug-drug interactions were the most commonly reported DRPs at 8.6%.

7. Counseling obligations for self-medication

The Federal Chamber of Pharmacists' guideline on quality assurance “Information and patient counseling - self-medication” (Fig. 1) and the accompanying commentary, describe the limits of self-medication, establish criteria for selecting and assessing the active ingredient as well as the appropriate dosage forms, and list aids and sources to support patient counseling on self-medication.^{23,24} These working tools deal with important indication areas of self-medication. Limits to self-medication treatment according to a guideline are shown in Box 1, criteria for selection and

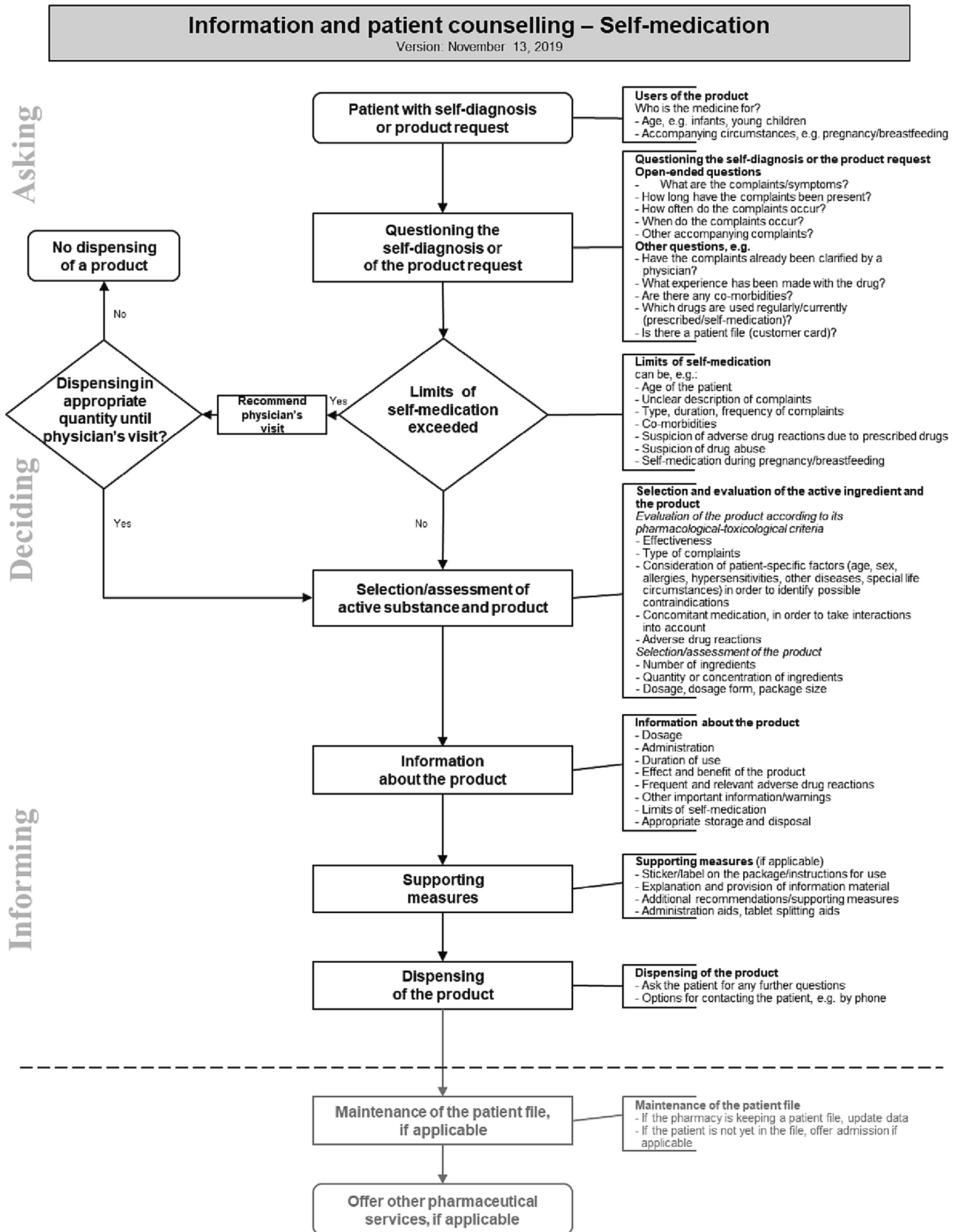


Fig. 1. Guideline of the German Federal Chamber of Pharmacists on information and advice on the administration of self-medication^{23,24}; ADR, Adverse drug reactions.

evaluation of the recommended self-medication drug in [Box 2](#), and important information in self-medication counseling in [Box 3](#).

Box 1

Limits to self-medication treatment may include.^{23,24}

- Age of the patient (too young, too old).
- Unclear description of symptoms.
- Type, duration, frequency of symptoms.
- A significantly more efficacious and/or safer prescription-only drug is recommended.
- Co-morbidities.
- Suspicion of adverse drug reactions due to prescribed drugs.
- Suspicion of drug abuse.
- Self-medication during pregnancy/breastfeeding.

Box 2

Criteria for selection and evaluation of the recommended self-medication drug.^{23,24}

- *Number of ingredients*: Evaluation of the usefulness of combinations.
- *Quantity or concentration of ingredients*.
- *Dosage*: Checking whether the dosage recommended is effective for the – claimed – indication.
- *Dosage form*: Appropriate for the patient, e.g. use in children? Tube use?
- *Package size*: Estimate duration of therapy.

Box 3

Important information in self-medication counseling.^{23,24}

- No combination with alcohol and/or certain foods.
- Influence on reaction capability: possible/probable.
- Avoid UV light or use adequate UV protection.
- Impairment of the efficacy of (oral) contraceptives.
- Behavior in case of pregnancy.
- Appropriate storage, e.g. keep medications in a cool and dry place or, if necessary, in the refrigerator.
- Shelf life and use-by date after opening.
- Instructions for cleaning, e.g. of dosage aids.
- Disposal of medications, syringes, and needles.

The policy paper “Pharmacy 2030”,²⁵ in which the pharmacy community has laid down its vision for their role as healthcare professionals in the coming decade, includes a participatory decision-making process as well as “informed consent” between pharmacists and patients: “In the interest of patient welfare and the relationship of trust, CPs consider the wishes and needs of their patients and advise them directly in a personal, individual, comprehensive manner, free of coercion and independent of third-party interests”. This professional paper does not specifically address issues with regard to WHO’s seven pillars of self-care.

8. Impact of direct-to-consumer marketing

OTC-products are frequently advertised as part of direct-to-consumer marketing, which is not allowed for prescription-only medicines.¹ In addition, mail-order sales of medication have been permitted since 2004 and have by now achieved a double-digit market share for OTC-medicines.¹ [Box 4](#) gives an overview of mail order business for German self-medication. The competitive behavior and advertising of mail-order

companies are primarily price-focused and encourage the trivialization of medicines. Their actual therapeutic purpose and the associated risks are thus pushed into the background and played down. The advertising pressure means that patients often attend CPs with a preconceived wish for a branded product, which makes symptom- and complaint-oriented information and counseling more difficult. In addition, many patients who order online completely forgo the professional advice to which they are entitled.¹

Box 4

Mail order business for German self-medication: “20–20–20”.³⁴

In Germany, the mail order business for pharmaceutical products has been in existence for almost 20 years. In terms of self-medication, this has a market share of around 20%. As a rule, there is a price advantage of 20% on average compared to on-site pharmacies. Experts therefore advise that the OTC markets online and on-site should be considered separately - also because of the different target customers. Differences can also be found in purchasing conditions, sources of supply and target groups, but the most important difference is the habits of the respective customers, who buy less because of price advantages than because of their habits. Sales prices should, therefore be calculated commercially, also to cover rising cost.

9. Regulatory aspects

Before medications can be marketed, their efficacy, safety, and quality have to be proven.¹¹ This generally also applies to OTC-medications. In Germany, there are various options for market access for OTC-drugs²⁶: Firstly, since 1978 it has been possible to exempt definitive drugs from the approval requirement under the German Medicines Act on the basis of standard approvals. The prerequisite for this, however, is that there are no safety issues. Secondly, the German Medicines Act includes drugs of special therapeutic directions. These include homeopathic, anthroposophic, and herbal (phytotherapeutic) therapeutic directions. For the first two, the context of the therapeutic direction is taken into account and no scientific evidence of efficacy is required. These are not approved for a specific indication, but only registered. Thirdly, the process for traditional medicines differ from other medicinal products in that their efficacy is based exclusively on traditional use. Fourthly, other products such as cosmetics and dietary supplements are also on the market, but these are not subject to approval and do not need to have any efficacy data.

Fifthly, the so-called “switch medications” to pharmacy-only status, that is medications that have been switched from prescription-only, which have already been approved and proven in efficacy and post-marketing safety¹. If they have not previously approved with non-prescription status within the European Union, the German Federal Ministry of Health decides on Rx-to-OTC-switches based on the recommendations of the Expert Committee on Prescription-only Drugs. A switch may apply only after a minimum time of three years after (EU) prescription-only approval by the end of 2016. More than 130 active ingredients had been switched from the prescription-only to pharmacy-only obligation and more than 30 alone since 2005. This has expanded the opportunities for CPs to make recommendations to their patients for self-medication and has also increased the importance of advice provided by CPs. Additionally, if more medicines are subject to OTC/pharmacy-only-status, that are also complex to use and require intensive consultation, this will increase the importance of the CP for consumer protection.¹

10. Pharmacovigilance

Adverse events (AE) associated with self-medication leading to hospitalization in internal medicine departments was studied in a multicenter

observational study covering a hospital catchment area of approximately 500,000 inhabitants.²⁷ The causality of the AE was also evaluated using the relevant algorithm of Bégau (at least “possibly” medication-related). Of 6887 admissions with AEs, self-medication was involved in 266 (3.9%) patients. In 143 (53.8%) of these patients, the AEs were due to OTC-products. Most of the AEs were related to self-medication occurring in women aged 70–79 years and in men aged 60–69 years and were predominantly gastrointestinal complaints caused by nonsteroidal anti-inflammatory drugs (most commonly OTC-aspirin). Drug-drug interaction between a self-medication and a prescribed medication commonly involved aspirin as an OTC medication in addition to prescription-only diclofenac, occurring in 102 (38.3%) of patients.²⁷

11. Communication with customers

A study with CP customers in Germany aimed to explore their opinions and expectations regarding self-medication advice. In a cross-sectional survey, passers-by on the street were interviewed using a structured questionnaire.²⁸ From 963 respondents, 92% stated that they were generally satisfied with the counseling received in CPs regarding self-medication. About one-fifth reported they would like to be asked more health-related questions (22%) and to receive more information about non-prescription medications (20%). Privacy issues (39%) and reluctance to talk about certain conditions (43%) were the most common reasons for refusing in-depth counseling. Respondents understood the need to answer the questions recommended in the guidelines (85–96%) and did not mind being asked these questions (70–96%). Most respondents expected to be advised, even if they did not ask for it directly (69%). Furthermore, CPs were expected to recommend the most appropriate medication even if it was not what the customer originally had requested (87%). However, more than half considered advice unimportant if they knew exactly what medicine they wanted to buy (56%) or if they had used the non-prescription medication previously (70%). The majority also expected to receive guideline-based drug information (52%).²⁸

A further study was performed to explore the opinions of pharmacists using self-assessment questionnaires and observation of customer interactions in CPs. The authors showed that in actual routine care comparatively few parameters of information guidelines were addressed. This was attributed to a perceived “disinterest” of patients in receiving counseling. These findings should encourage to question whether customers/patients are actually uninterested in counseling and to further explore how pharmaceutical staff's positive intent toward information exchange can be further implemented in daily practice of self-medication.

A similar design was chosen by Moritz et al.²⁹ In this study, most of the pharmaceutical staff recognized the importance of including findings from clinical studies in self-medication advice. Based on self-report, however, clinical trial data were not taken routinely into account in counseling practice with a minor proportion of staff routinely dealing with clinical trials.³⁰ Pharmaceutical staff were satisfied with 85% of their own consultations and 76% were perceived as easy to handle. However, the exchange of information in observed consultations on self-medication guideline was not optimal.³⁰

Moritz et al.²⁹ characterized, using independent monitors of consultations in CPs, OTC-medication communication based on three evidence-based criteria (outcome variables: scientific evidence such as clinical trial results, pharmaceutical staff experience, and customer experience). In 379 observed counseling sessions, 300 OTC-medications were recommended by the pharmacy staff and 390 were requested by customers. The least considered criterion was scientific evidence (for OTC-products recommended by pharmaceutical staff) followed by pharmaceutical staff experience. Customer experience was addressed more frequently. It might be worth considering as mentioned previously more carefully delineating roles of pharmacists' in communication with patients taking herbal and dietary supplements.^{31–33}

Unscheduled visits and performance feedback by trained pharmacists as pseudo customers following the consulting process are continuously

applied by Chambers of Pharmacists in CP practice.³⁴ During the conversation, the pseudo customer observes and evaluates the advice given by the pharmacy staff on the basis of predefined quality criteria, defined by the German Federal Chamber of Pharmacists. After the consultation, the pseudo customer leaves the CP and then documents the conversation by means of a standardized checklist, which includes professional and communicative evaluation aspects. Immediately afterwards, a discussion takes place in the CP with the consultant alone and then together with the pharmacy manager or the responsible pharmacist. In this way, the pharmacy staff receives direct, constructive feedback, which at the same time includes individual coaching. In addition, the pharmacy receives written feedback with the most important strengths and potential for improvement as well as the change measures developed.³⁵

12. EVInews providing evidence

To support pharmacists in providing self-medication advice based on evidence, the ABDA - Federal Union of German Associations of Pharmacists¹³⁶ developed an electronic newsletter and database (EVInews). By free-of-charge subscription, pharmacists receive a monthly published newsletters via email and can access all contents via a database (<http://www.evinews.de>).

The aim is to provide evidence-based information for CPs on commonly used OTC-medicines and guidance on how to search and appraise scientific literature.³⁷ In April 2023, there were nearly 4265 subscribers and more than 78 newsletters published [data on file]. Subscribers were surveyed in an anonymous online cross-sectional survey approximately one year after the first newsletter was published. Most of them found the summarized information useful. They attributed positive changes in knowledge, skills, awareness, and motivation to the newsletters. However, nearly half found it difficult to integrate reading the newsletter during their daily work routine.³⁷

This challenge was addressed through a change in the second phase of the project. Summary tables, an assessment of evidence quality using standard checklists, and conclusion texts were used to increase the practical relevance. A recent study showed that participants who used EVInews performed better when confronted with self-medication related search queries than when using web-based information sources of their choice in the context of health-information quality and evidence-based counseling [data on file].

13. Conclusions

Self-medication plays an important role in the German healthcare system. Counseling in CPs has proven to prevent and to solve DRPs. Self-medication has a high significance for CPs in terms of dispensing volume and, to a lesser extent, turnover. Legal regulations and professional guidelines provide a high standard of information and consultation. However, advertising and internet trade has created pressure on the counseling quality in CPs. Self-medication/OTC-products can be considered “goods of a special kind” and their inappropriate use can be risky. In order to fulfill their role, clinical evidence should be taken into account to a greater extent by CPs. In the future, available professional standards and information about self-medication should be better implemented in routine practice.

Declaration of Competing Interest

TB is responsible for the pharmaceutical content of EVInews which is funded by ABDA – Federal Union of German Associations of Pharmacists, Berlin, Germany. JMA has developed content for EVInews. CE is an employee of ABDA. MS is an employee of ABDA; he received honoraria for lectures/consulting from Bristol Myers Squibb, Chambers of Pharmacists, CSL

¹ ABDA - Federal Union of German Associations of Pharmacists is the German umbrella organization consisting of the 17 State Chambers of Pharmacists (mandatory membership of all pharmacists) and the 17 State Associations of Pharmacists (CP owners only and voluntarily).

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