Priv.-Doz. Dr. med. Tobias Jäger
Dr. oec. publ. Matthias Arnold MBA
Prof. Dr. oec. publ. Dominik Rottenkolber

Discharge from the prescription requirement in Germany and the United Kingdom

A comparison using the example of the active ingredient sildenafil 50 mg

Summary

This article examines the removal of medicines from prescription-only status and the switch to over-the-counter (OTC) medicines. In recent years, many countries such as the United Kingdom and Poland have authorised OTC status for sildenafil 50 mg. This decision is primarily based on analyses of the safety profile and potential for abuse, but also on public health considerations. In Germany, on the other hand, sildenafil is currently only available on prescription, which indicates different regulatory assessment standards.

The comparison of the assessments in the United Kingdom and Germany shows that in Germany the side effects of the active substance were emphasised as a significant limitation to patient safety, while in the United Kingdom patient safety in OTC dispensing by pharmacies was assessed as sufficiently guaranteed. The potential OTC release of sildenafil may offer numerous benefits, including improved patient autonomy and a reduction in the burden on healthcare providers. This may lead to safer access to high quality medicines and better detection and treatment of underlying conditions by doctors and pharmacies. The article highlights the importance of harmonised evaluation standards for the removal of the prescription requirement and the consideration of public health aspects.

Keywords

Compulsory prescription, pharmacy authorisation, public health

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In recent years, the prescription requirement for numerous active substances has been lifted at national and international level (e.g. triptans, antihistamines or H2 receptor antagonists). The 'triage criteria' are centred on '[...] safe and easy use, [the] strengthening of patient responsibility and [an] improved quality of life' (1). Self-medication with procurement of the medicine via the pharmacy can also lead to positive effects for the healthcare system (2).

Criteria for release from the prescription requirement

>> The regulatory decision to remove the prescription requirement for medicinal products and transfer them to over-the-counter (OTC) status is based on different criteria depending on the authorising authorities. If the marketing authorisation holder has a central marketing authorisation in accordance with EC Regulation No. 726/2004, the responsibility for removing the prescription requirement falls to the European level and is carried out in accordance with the 'Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use' (3).

If an active substance has been authorised nationally in Germany, the relevant regulations can be found in Section 48 of the German Medicinal Products Act (4). In Germany, Annex 1 of the Ordinance on the Prescription-only Use of Medicinal Products (AMVV) is amended accordingly by a statutory order (issued and amended by the Federal Ministry of Health in agreement with the Federal Ministry of Economics and Technology and with the final approval of the Federal Council and promulgation of the amended ordinance in the Federal Law Gazette) and active substances are thus released from the prescription requirement (5). Upon application, a decision is initiated by the Federal Ministry of Health, which is based on a recommendation by the Expert Committee for Prescription-only Medicines of the Federal Institute for Drugs and Medical Devices (BfArM).

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) decides on the change of a medicinal product from prescription-only medicine to OTC status (pharmacy medicine). The relevant criteria for this are set out in regulation 62(3) of the Human Medicines Regulations 2012 (6), which are recognisably based on the corresponding European guideline (3)..

The decision criteria of the EU guideline define situations in which a prescription is required. In accordance with this requirement, active substances for which the prescription requirement is to be cancelled must prove their safety in all criteria (see Table 1).

Firstly, it is assessed whether the medicinal product can be used safely without medical supervision and whether the dosage and administration recommendations stated on the packaging can be followed. Consumers must be able to correctly diagnose the area of application on their own and determine when medical intervention may be required. The risk of interactions with other medicines or substances as well as appropriate warnings and precautions to minimise risk should also be included in the assessment. In addition, data on known adverse drug reactions reported during the clinical trials and post-marketing surveillance will also be reviewed. Finally, the potential benefit-risk ratio with regard to OTC use is weighed up (criterion 1).

This is followed by an assessment of whether the drug has a potential for abuse or addiction, particularly with regard to long-term use. The pharmacological properties of the active substance, its similarity to other medicinal products with abuse potential and any indications of misuse are examined. Assessments of the risk of accidental or deliberate overdose are also included in the evaluation (criterion 2).

If new active substances have only recently been authorised and the evidence base is therefore not yet sufficient, as theeffect and/or side effects require further investigation, OTC approval should not be granted (criterion 3).

OTC release should also be refused if medicines are normally prescribed by a doctor for parenteral administration (i.e. injection) (criterion 4).

Kriterien der EU-Guideline zur Änderung der Einstufung für die Abgabe eines Humanarzneimittels (3)	
Kriterium	Beschreibung
Kriterium 1	Arzneimittel unterliegen der ärztlichen Verschreibungspflicht, wenn sie auch bei bestimmungsgemäßem Gebrauch eine unmittelbare oder mittelbare Gefahr darstellen können, sofern sie ohne ärztliche Aufsicht verwendet werden.
Kriterium 1.1	Unmittelbare Gefahr/Sicherheitsprofil
Kriterium 1.2	Mittelbare Gefahr/Sicherheitsprofil
Kriterium 1.3	Selbstbeurteilung
Kriterium 1.4	Risiken und Folgen einer falschen Anwendung
Kriterium 1.5	Patienteninformation
Kriterium 2	Arzneimittel unterliegen der ärztlichen Verschreibungspflicht, wenn sie häufig und in großem Umfang unsachgemäß verwendet werden und dadurch eine unmittelbare oder mittelbare Gefahr für die menschliche Gesundheit darstellen können.
Kriterium 2.1	Bekannte unsachgemäße Verwendung
Kriterium 3	Arzneimittel unterliegen der ärztlichen Verschreibungspflicht, wenn sie Stoffe oder Zubereitungen enthalten, deren Wirkung und/oder Nebenwirkungen weitere Untersuchungen erfordern.
Kriterium 3.1	Kurze Zulassungsdauer/begrenzte Erfahrung
Kriterium 3.2	Neue Stärke, Dosis, Art der Verabreichung, Indikation, neue Altersgruppe oder Kombination von Stoffen
Kriterium 4	Arzneimittel unterliegen der ärztlichen Verschreibungspflicht, wenn sie normalerweise von einem Arzt/einer Ärztin zur parenteralen Verabreichung (zur Injektion) verschrieben werden.

Tab. 1: *Criteria of the EU guideline for changing the classification for dispensing a medicinal product for human use (3).*

Erectile dysfunction as a relevant public health problem

Internationally, however, OTC switch procedures have been successfully carried out in the UK, Norway and Ireland (50 mg each) as well as Poland (25 mg/50 mg), Switzerland (25 mg) and New Zealand (25 mg/50 mg/100 mg). Using the example of the regulatory decision on the standard dose of 50 mg (14), the assessments of the two authorisation authorities in Germany and the United Kingdom will be compared (see Table 2).

The comparative presentation reveals the different assessments of the facts (particularly with regard to the safety profile of sildenafil 50 mg) from the respective national perspectives. It is important to note that for the MHRA, taking into account the contraindications, the benefits of the drug outweigh the risks.

Public health impact of a possible OTC release of sildenafil 50 mg

However, the cancellation of a prescription requirement cannot be viewed solely from a regulatory perspective. Rather, the public health perspective must also be taken into account. The focus here is on maintaining the health of '[...] individual population groups through organised social action' (17), i.e. on the health effects at the patient-relevant level (morbidity, health-related quality of life or side effects) and their far-reaching effects at the level of the healthcare system (18).

This consideration is not limited to safety aspects of the active substances to be released, but also takes into account the effects of possible access to these medicines and the control of possible black market activities. In addition, the relevance of indirect effects on the supply system, e.g. by relieving the burden on the medical profession, is assessed.

The safety and efficacy of sildenafil have been well documented in numerous studies (19, 20). Numerous positive effects and public health effects (e.g. improvement in men's health awareness or screening and identification of previously untreated diseases) were already associated with the market launch (21).

Controlled access to non-prescription medicines via local pharmacies can be a starting point for curbing the misuse of medicines (22, 23). Younger men in particular who are inexperienced in treatment regularly obtain sildenafil (or preparations that are supposed to contain the active ingredient) via the Internet (24, 25), often without the possibility of direct contact with a doctor (26). The fact that erectile dysfunction has been clearly identified as a predictor of underlying diseases appears to be particularly problematic. However, it is precisely here that there is considerable potential for improving care through an OTC switch, as this population group is otherwise outside the contact options with the healthcare system and rarely receives professional advice beyond standardised internet forms. A primary risk assessment with regard to inappropriate use in patients who are not suitable for sildenafil treatment or use in combination with contraindicated drugs (e.g. nitrates (27)) can be successfully carried out in pharmacies, as experience from other EU countries shows.

Illegal sources of supply lead to those affected treating their erectile dysfunction themselves without prior contact with health professionals, which is associated with considerable direct (through counterfeit or contaminated active ingredients) risks.

or contaminated active ingredients) and indirect risks (through lack of interaction with health professionals) (28). Sildenafil and other PDE5 inhibitors are among the most commonly counterfeited medicines, accounting for up to 80% of all seized illicit medicines both in Europe and worldwide (29-31), and their use is associated with an increased risk of side effects (32, 33). These figures emphasise the importance of reliable supply chains, which can only be guaranteed via pharmacies.

A clearly stated advantage of OTC release is the strengthening of the medical expertise of pharmaceutical staff through sound and expert counselling services. Pharmacies thus '[...] also make a [public health-relevant] social contribution as mediators and networkers' (34). The necessary expertise within pharmacies is guaranteed. The results of a European observational study showed a high level of agreement between pharmacists and general practitioners (73%) and

Vergleich der Bewertungsverfahren zu Sildenafil 50 mg in Deutschland und dem Vereinigten Königreich		
Kriterium	**Deutschland (15)**	**Vereinigtes Königreich (16)**
1: Direkte oder indirekte Gefahr für die menschliche Gesundheit (auch bei sachgemäßer Anwendung)	„Die Daten zeigten eine erhebliche Anzahl von schwerwiegenden Nebenwirkungen in klinischen Studien bei der 50-mg-Dosisstärke, aus denen sich erhebliche Nebenwirkungszahlen nach Marktzulassung ableiten ließen, ohne dass diese entsprechend gemeldet und erfasst werden würden. Zudem erforderten die Kontraindikationen eine ärztliche Abklärung, die durch Apotheker nicht vorgenommen werden kann." „Die kardialen Risiken seien unzureichend berücksichtigt. Die möglichen Blutdrucksenkungen könnten bei entsprechend vorbelasteten Patienten zu schwerwiegenden Problemen führen." „(Schulungs-)Materialien für Patienten und Apotheker – keine Selbstmedikation durch zusätzliche risikominimierende Maßnahmen – Schulungsmaterial könnte nicht über AMVV geregelt werden."	Direkte Risiken können bei der Apothekenabgabe auf ein akzeptables Maß reduziert werden. Es besteht ein geringes Risiko der Verschleierung von Grunderkrankungen („indirekte Gefahr"). Dieses Risiko wird jedoch durch das angebotene Versorgungsmodell minimiert und durch die Vorteile aufgewogen, die sich daraus ergeben, dass die Patienten Zugang zu einer legalen Versorgung durch Apothekerinnen und Apotheker haben, die sie in Gesundheitsfragen beraten und gegebenenfalls an die Hausärztin oder den Hausarzt verweisen können. Die gleichzeitige Einnahme von Sildenafil mit Amylnitrit oder jeglichen Nitraten wird in der Fachinformation unter Kontraindikationen gelistet, was nach Ansicht der MHRA eine akzeptable Risikominimierungsmaßnahme darstellt.
2: Häufige und in sehr großem Umfang unsachgemäße Verwendung (d. h. Sucht, Abhängigkeit, Freizeitkonsum und Missbrauch) resultiert in einer direkten oder indirekten Gefahr für die menschliche Gesundheit.	„Missbrauchsrisiko vorhanden – Schwelle für Anwendung von Sildenafil bei (jungen) Männern ohne ED [erektile Dysfunktion] würde bei einem OTC-Status sinken". „- Psychische Abhängigkeit – Anwendung durch Männer ohne ED ‚zur Sicherheit'/ trauen sich sexuelle Aktivitäten ohne Einnahme nicht mehr zu - Bedeutung beim ‚Chemsex' (freiwillige Einnahme psychoaktiver und nicht psychoaktiver Substanzen im Rahmen von z. B. Sexpartys), um - lang andauernde sexuelle ‚Einsatzfähigkeit' zu ermöglichen - Impotenz verursachende Wirkung anderer Substanzen wie Kokain, Antidepressiva zu ‚neutralisieren'".	Klinische Daten lassen nicht erkennen, dass Patienten eine Abhängigkeit oder Sucht entwickeln. Die Einnahme von illegal erworbenem Sildenafil (oder unter diesem Label verkauften Wirkstoffen) durch Personen ohne erektile Dysfunktion ist hinlänglich beschrieben. Die MHRA hält es zumindest für diskutabel, ob diese Anwendergruppe nach einem OTC-Switch eher zu einem Bezug über die Apotheke tendiert. Es scheint jedoch kaum Anhaltspunkte dafür zu geben, dass dieser absichtlich unsachgemäße Gebrauch zu einer direkten oder indirekten Gefährdung der Gesundheit führt.
3: Medikament enthält Stoffe oder Zubereitungen von Stoffen, deren Wirkung oder Nebenwirkungen weitere Untersuchungen erfordern.	Keine Aussage.	Das Sicherheitsprofil von Sildenafil ist aufgrund der langen Zulassungsdauer und Verschreibungspflicht sehr gut erforscht. Weitere Untersuchungen werden seitens der MHRA für nicht erforderlich gehalten. Sildenafil erfüllt in Bezug auf Kriterium 3 nicht die Anforderungen an eine ärztliche Verschreibung.
4: Ärztliche Verschreibung zur parenteralen Verabreichung (d. h. Injektion).	Sildenafil wird als Tablette verabreicht, sodass Kriterium 4 nicht zutrifft.	Sildenafil wird als Tablette verabreicht, sodass Kriterium 4 nicht zutrifft.

Tab. 2: *Comparison of the assessment procedures for sildenafil 50 mg in Germany and the United Kingdom.*

sexual medicine specialists (91%) regarding an appropriate recommendation for sildenafil 50 mg. Overall, counselling of patients with erectile dysfunction in pharmacies resulted in accurate treatment recommendations, no dispensing of sildenafil to men not suffering from erectile dysfunction, and referral to medical treatment for questions about cardiovascular health, other comorbidities or concomitant medication (35). As only an estimated 10-20% of affected men over the age of 50 consult a medical practice (36), this offers a starting point for access to the healthcare system via pharmacies in the context of the OTC availability of sildenafil.

Specialist medical consultations are subject to enormous economic pressure, whereby the remuneration structures do not adequately reflect the high amount of time required for the diagnosis and treatment of erectile dysfunction (37). At the same time, the need for urological care is likely to increase by 20% over the next two decades due to demographic changes. In the next 15 years, two thirds of urologists in private practice will retire from active practice, which increases the risk of underuse (38). The relief for

urological practices resulting from the OTC release of sildenafil could therefore represent a further advantage, as it is unlikely that the increasing shortage of specialists and the declining willingness to set up practices can be remedied in the foreseeable future (39, 40). The use of existing medical resources should therefore be as efficient as possible in terms of maximising the health of the population as a whole: 'If in future more patients with minor illnesses [...] visit a pharmacy instead of a doctor's surgery, this will save the doctor time and money and generate an optimisation of resources in the healthcare system [...] [which] not only makes sense from a health economic and social point of view, but is also necessary in order to continue to guarantee these treatments for people with illnesses that require medical treatment [...]'. (34) Empirical studies have shown that intensifying self-care could save an average of one hour of working time per day per GP, which would lead to an increase in consultation time of up to 25% on an individual patient level and could lead to both improved diagnostics and therapy (2). Current health policy endeavours are moving in a similar direction, calling for more personal responsibility on the part of patients.

Conclusion

To summarise, it is clear that the criteria for lifting the prescription requirement are interpreted differently in the national decision-making bodies. The examples of the conflicting OTC decisions on sildenafil 50 mg and also 25 mg show that the balance between therapeutic safety and public health impact is apparently assessed differently in Germany than in some neighbouring European countries, particularly the United Kingdom. As can be seen from the available public documents, the public health perspective is not sufficiently recognised in Germany.

OTC release can facilitate access to sildenafil and at the same time ensure that users have access to high-quality medicines and do not have to use non-transparent sources. Pharmacy counselling services would ensure low-threshold access to the healthcare system, especially in rural areas where access to medical care may be limited. In addition, the removal of the prescription requirement can help to refer affected individuals to specialist care earlier by giving pharmacies a central role in recognising risks and underlying conditions and making a preventative contribution to men's healthcare. <<

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Priv.-Doz. Dr. med. Tobias Jäger ORCID:0009-0000-7100-9342



studied human medicine at the Ruhr University Bochum and the University of Duisburg-Essen as well as business administration for physicians in Cologne. He specialises in urology and habilitated in urology at the University of Duisburg-Essen. Dr Jäger is a senior partner at the Urological Practice Clinic Essen.

Contact : Jaeger@upk-essen.de

Dr. oec. publ. Matthias Arnold MBA ORCID: 0000-0002-9736-7233



is a member of the management board of inav GmbH. He holds a doctorate in health economics from the LMU Munich. He also holds degrees as Master of Business Research (LMU Munich), MSc. Global Health and Development (UCL) and a degree in economics (University of Heidelberg). Dr Arnold is an expert in evaluation, research design and quantitative methods. He focuses on health economic evaluations, data analyses and studies for health care concepts in complex settings. Contact: Arnold@inav-berlin.de

Prof. Dr. oec. publ. Dominik Rottenkolber ORCID: 0009-0000-4028-5774



is Professor of Health Economics and Health Policy at the Alice Salomon University of Applied Sciences Berlin. He previously held various positions in public and private healthcare organisations. His research and work focusses on health and care economics as well as pharmaceutical economics and pharmaceutical economics.

Contact: Rottenkolber@ash-berlin.eu