

## Regulatory Access to PDE-5 Inhibitors and Its Impact on Erectile Dysfunction Management: A Cross-National Study

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### Abstract

This research explored how different prescription rules for phosphodiesterase-5 inhibitors (PDE-5Is) influence the handling of erectile dysfunction (ED) among men. A total of 10,000 men from Germany, Norway, Poland, and Switzerland participated in a survey that used the International Index of Erectile Function questionnaire. The tool helped detect men with ED and collect information about their treatment choices and personal experiences. The study also looked into the use of PDE-5 inhibitors among men who did not have ED.

A larger share of men with ED used PDE-5Is in Norway and Poland, where the drugs are sold over-the-counter, and in Switzerland, where they are dispensed by pharmacists, compared with Germany, where a doctor's prescription is mandatory. In every country surveyed, pharmacy staff recommended that men considering buying PDE-5 inhibitors speak with a physician. Reliance on black-market sources for PDE-5 Inhibitors remained very low in areas where non-prescription purchase was permitted. Non-medical use of these medications was rare across all regions. Requiring a prescription for PDE-5 inhibitors can discourage men from pursuing treatment for ED and from identifying related health problems. For this reason, PDE-5Is should be made available without a prescription to strengthen ED care and motivate men to engage more actively with healthcare services.

**Keywords:** Phosphodiesterase-5 inhibitors (PDE-5Is), Erectile dysfunction, Erectile function questionnaire, Men

### Introduction

The World Health Organization has underlined the significance of sexual health as a key contributor to the physical and emotional well-being of people, couples, and families. Despite this, men's health issues have not received sufficient focus [1, 2]. Since 2009, conditions such as erectile dysfunction (ED) have drawn increased interest after researchers identified a connection between ED in younger men and a higher long-term risk of cardiovascular (CV) problems. ED refers to the persistent

inability to obtain or sustain an erection that is adequate for fulfilling sexual activity, often leading to major effects on sexual function and general well-being [1, 3]. Findings from the National Health and Social Life Survey indicate that sexual dysfunction is tied to reduced physical and mental health, along with lower quality of life (QoL) [4, 5]. In addition, ED commonly stems from cardiovascular diseases, hormonal imbalances, or depression [6] and appears in both individuals living with chronic illnesses and those who seem otherwise healthy [7].

Phosphodiesterase-5 inhibitors (PDE-5Is) are recognized as the preferred initial treatment for ED and are recommended by the American Urological Association as well as the European Association of Urology [8]. Examples include sildenafil (Viagra, available since 1998), tadalafil (Cialis, available since 2003), vardenafil (Levitra, available since 2003), and avanafil (Stendra,

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available since 2012), all of which have official approval for the management of ED [8].

Even though ED and associated health concerns are widespread, numerous men still hesitate to seek help because of personal, social, and informational obstacles involving doctors, patients, and their partners [9]. A large number of men feel uncomfortable visiting a doctor or openly admitting they have ED. More than 70% of ED cases go undiagnosed owing to this reluctance, despite the condition being a major worldwide health concern [10]. As a result, chances for early prevention and effective management of both ED and any underlying disorders are frequently missed [5, 11].

The ease of obtaining PDE-5Is plays a major role in how often they are used to treat ED. In certain countries, such as Poland, Norway, New Zealand, Ireland, and the United Kingdom, sildenafil and/or tadalafil can be bought from pharmacies without needing a prescription. By contrast, most other nations continue to treat PDE-5Is as prescription-only drugs [12]. When legal access is restricted, some patients turn to unauthorized channels to acquire PDE-5Is [13, 14], thereby skipping regular medical evaluations for co-existing conditions.

Consequently, it is important to study how men actually behave when dealing with ED. Such an investigation can provide valuable knowledge about treatment patterns and help reveal hidden serious conditions linked to ED — including diabetes, hypertension, coronary artery disease, and depression — at an earlier point.

The present study assembled in-depth information on the frequency of ED and on men's approaches to managing it. We specifically assessed whether differences in prescription requirements for PDE-5Is affected the quality of care and treatment received by men with ED. Countries with contrasting policies were compared: doctor-issued prescription only (Germany, DE), fully over-the-counter (Poland, PL; Norway, NO), and pharmacist-issued prescription (Switzerland, CH). This comparison allowed evaluation of the advantages and potential drawbacks of each regulatory model for patients living with ED. The findings shed light on both actual treatment uptake and the opportunity to promptly detect underlying health issues, such as cardiovascular disease.

## Materials and Methods

### *Study design*

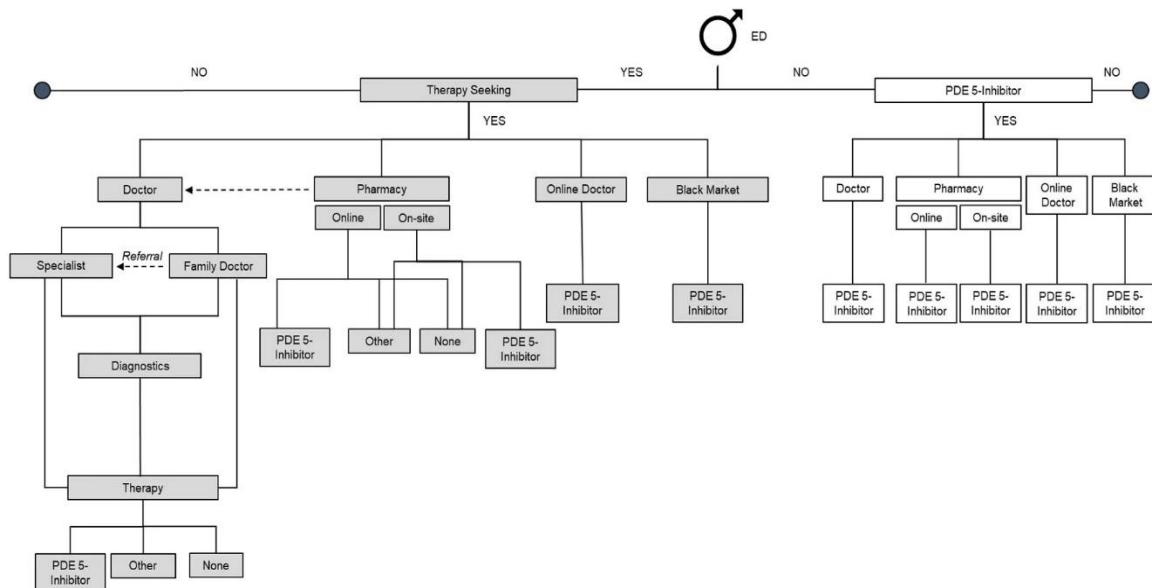
An online representative survey was conducted between April 14, 2023, and May 5, 2023, among male participants from four countries: DE, NO, PL, and CH. Altogether, 10,000 men from these countries were screened.

### *Participant selection*

Slightly more individuals than necessary were drawn from online panels using quota sampling designed to match national population profiles according to Eurostat (2021 data). Quotas were set based on the age and regional distributions of males aged 18–75 years in each country. All participants gave their informed consent under the General Data Protection Regulation before completing the questionnaire. They explicitly agreed to the collection of personal data on their health and sexual life. They permitted the sponsor to receive reports of any adverse events (AEs) or product quality complaints. Eligible respondents who passed the screening stage then received the full survey questionnaire. The main questionnaire gathered information on: detection of ED, willingness to seek treatment and consideration of options for ED symptoms, discussions with healthcare professionals (HCP) (doctors or pharmacists) about ED matters, medical examinations or treatments obtained for ED symptoms, barriers preventing consultation with a doctor, actual use of PDE-5Is, and the various channels used to obtain these medications. Data collection continued until the desired sample sizes were reached across all regions, age brackets, and other demographic segments.

### *Sampling and data collection*

Specialized sampling software selected suitable panel members who aligned with the target population profile for males in each country. Panelists received a broad invitation that routed them to the survey. Access was also possible directly through the panel website or mobile application dashboard. Behavioral patterns among men in the ED category and the flow of decision-making pathways were mapped and analyzed (**Figure 1**).



**Figure 1.** Decision tree (Germany 2025). ED, erectile dysfunction; PDE-5i, phosphodiesterase-5 inhibitor. The average interview duration was 12 min. Any adverse events connected to the products were systematically recorded.

### Scoring

ED status was determined using the International Index of Erectile Function (IIEF-5), a 5-item questionnaire. Responses to each item were scored on a 0–5 scale (first item scored 1–5), producing an overall score from 0 to 25 points. A score of  $\leq 21$  indicated the presence of ED. Severity levels were defined by IIEF-5 scores as follows: mild (17–21), mild-to-moderate (12–16), moderate (8–11), and severe (1–7) [15, 16]. In addition, every participant answered a single closed-ended self-assessment question asking whether they personally considered themselves to have ED (self-reporter).

### Outcome measures

Groups of participants were created based on the collected information to meet the specifications of a decision analytic model. ED prevalence was expressed as the percentage of men who either self-reported ED or met the criteria for ED according to the IIEF-5 scoring system.

### Statistical analysis

Quota sampling aligned with Eurostat (2021 data) produced nationally representative samples by age and region for DE, NO, and CH. For PL, post-survey weighting was applied to the age distribution to better match Eurostat figures, as the 61–75 years age group was underrepresented. This survey weight (rim weighting

efficiency: 99.2%) was incorporated into all PL calculations. The analysis involved descriptive statistics, logistic regression, and Chi-square tests to examine differences between groups for binary outcomes. Ordinal logistic regression was used to analyze age categories. Multinomial regression assessed the link between having an ED and access to OTC medication. Every regression model was adjusted for age and country. Cases with missing data in regression analyses were removed using listwise deletion. For each regression, P-values, odds ratios (ORs), and corresponding confidence intervals (CIs) were presented, with significance defined as  $P < 0.05$ . All statistical processing was carried out in R, while data weighting procedures were performed in SPSS.

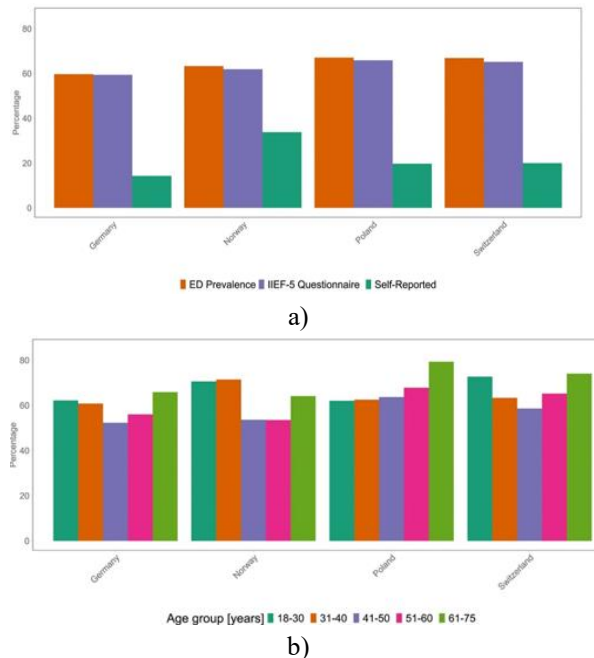
## Results and Discussion

### Prevalence of ED

In total, 10,000 men across the four countries completed the questionnaire, with exactly 2,500 respondents from each country. The mean age of participants was comparable across all nations: 46.3 years in DE, 45.1 years in NO, 45.0 years in PL, and 44.8 years in CH. The study identified 1,493 men with ED in DE, 1,582 in NO, 1,665 in PL, and 1,672 in CH.

ED prevalence differed significantly across countries depending on the evaluation approach. A high overall ED rate was observed in all countries (DE: 59.7%; NO:

63.3%; PL: 67.1%; CH: 66.9%). The rates based on IIEF-5 scoring were also quite close across the four countries (DE: 59.4%; NO: 61.9%; PL: 65.9%; CH: 65.2%). However, self-reported ED was significantly more frequent in NO (33.8%,  $P < 0.001$ ), PL (19.7%,  $P < 0.001$ ), and CH (20.0%,  $P < 0.001$ ) compared with DE (14.3%) (**Figure 2a**).



**Figure 2.** Incidence of erectile dysfunction in four different countries: (a) Erectile dysfunction prevalence (orange), as assessed by the International Index of Erectile Function-5 scoring system (purple), and erectile dysfunction self-reported by participants (dark green), (b) distribution of erectile dysfunction prevalence in the four countries by age group: dark green, 18–30 years; orange, 31–40 years; purple, 41–50 years; pink, 51–60 years; and light green, 61–75 years (Germany 2025). Abbreviations: ED = erectile dysfunction; IIEF-5 = International Index of Erectile Function.

#### Prevalence of ED in different age groups

ED prevalence remained elevated across every age bracket in all four countries, with both the youngest and oldest men showing higher rates than middle-aged men (**Figure 2b**). In DE, the highest prevalence occurred among those aged 61–75 years (65.8%), followed by the 18–30 years group (62.2%) and the 31–40 years group (60.8%). Lower figures were seen in the 51–60 years (56%) and 41–50 years (52.3%) brackets.

Although CH had a marginally higher overall prevalence, the age-related pattern closely mirrored that of DE. The peak was again in the 61–75 years group (74.0%), followed by 18–30 years (72.7%) and 51–60 years (65.2%), while the lowest rates appeared in the 31–40 years (63.3%) and 41–50 years (58.6%) groups.

In PL, ED prevalence rose steadily with advancing age, reaching the highest level in the 61–75 years group (79.3%), followed by the 51–60 years (67.8%). Rates for the remaining groups were 63.7% (41–50 years), 62.5% (31–40 years), and 62.0% (18–30 years).

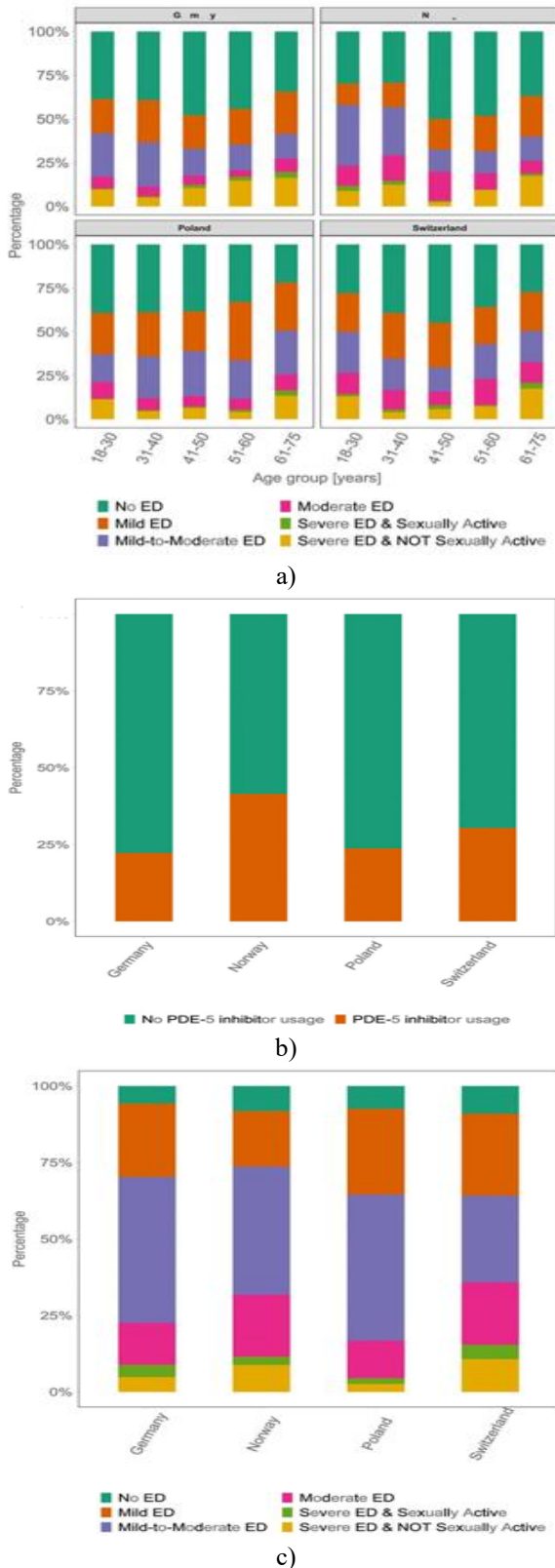
In NO, the pattern resembled DE and CH, with the lowest prevalence in middle-aged men: 53.5% for 51–60 years and 53.6% for 41–50 years. In contrast, the highest rates were found in younger men — 71.4% among those aged 31–40 years and 70.6% in the 18–30 years group. The oldest group (61–75 years) showed a prevalence of 64.1%.

#### Severity of ED

When evaluated using the IIEF-5 scoring system, the distribution of ED severity was consistent across all four countries. Most men experienced mild or mild-to-moderate ED, irrespective of age. Severe ED was the least frequent category, affecting  $\leq 4\%$  of participants across all age groups. Overall, the severity distribution closely tracked the prevalence trends observed across age groups. Higher severity was more common in the youngest men (18–30 years) than in the 31–40 and 41–50 years groups, before rising again among older participants (**Figure 3a**).

Despite broadly similar ED prevalence rates, clear differences emerged in the proportion of men receiving treatment. In DE, only 22.2% of men with ED reported using a PDE-5i. By comparison, significantly higher treatment rates were seen in NO and CH: 30.4% in CH (OR = 1.54, 95% CI [1.31, 1.80],  $P < 0.001$ ) and 41.5% in NO (OR = 2.34, 95% CI [2.01, 2.73],  $P < 0.001$ ). In PL, 24.1% of men with ED used PDE-5Is — higher than DE, but the difference did not reach statistical significance (**Figure 3b**).

The majority of PDE-5i users had mild-to-moderate ED. Notably, the category “severe ED and not sexually active” was more frequent in NO (8.8%) and CH (10.7%) than in PL (2.3%) and DE (4.9%). A parallel trend appeared for “severe ED and sexually active” (NO: 2.7%, CH: 4.7%, PL: 1.9%, DE: 4.0%) (**Figure 3c**).



**Figure 3.** Country-wise stages of erectile dysfunction severity and phosphodiesterase-5 inhibitors usage: (a) Prevalence and severity of erectile dysfunction across

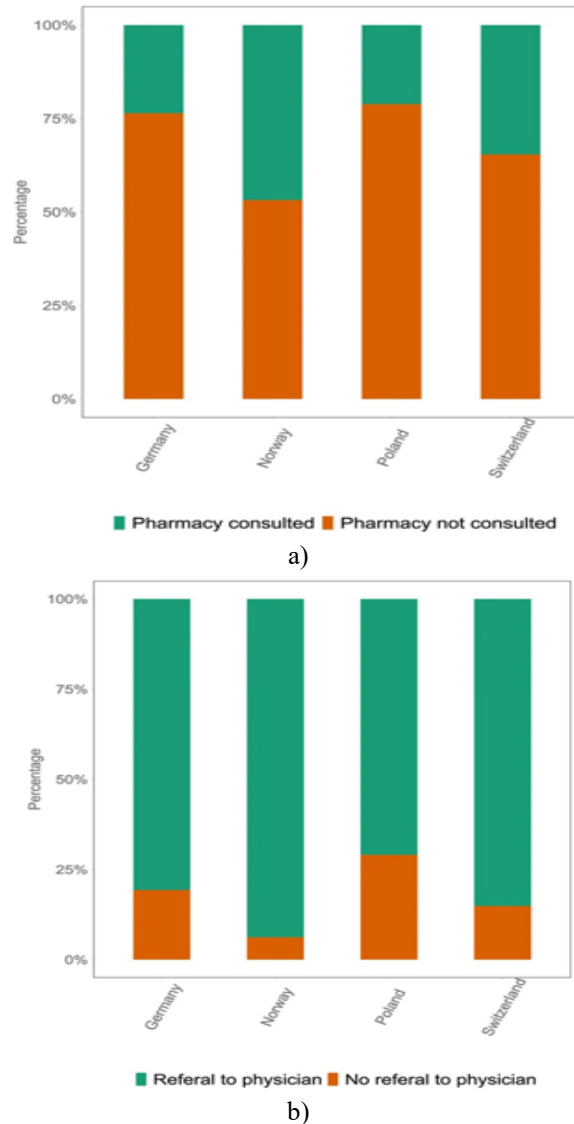
six age groups (18–30, 31–40, 41–50, 51–60, 61–75 years) for each country. The severity categories are color-coded as follows: no erectile dysfunction, dark green; mild erectile dysfunction, orange; mild-to-moderate erectile dysfunction, light green; moderate erectile dysfunction, purple; severe erectile dysfunction and sexually active, pink; and severe erectile dysfunction and not sexually active, yellow.

(b) Percentage of participants with erectile dysfunction who used phosphodiesterase-5 inhibitors compared with those who did not use phosphodiesterase-5 inhibitors. Data are represented as stacked bars for each country, with green and orange indicating no phosphodiesterase-5 inhibitor use and phosphodiesterase-5 inhibitor use, respectively. (c) Country-wise distribution of erectile dysfunction severity for participants on phosphodiesterase-5 inhibitor therapy. The bars are divided into categories of erectile dysfunction severity; color-coded as in panel (a) (Germany 2025). Abbreviations: ED = erectile dysfunction; PDE-5i = phosphodiesterase-5 inhibitor.

In Germany, only 39.3% of men experiencing ED had discussed erection difficulties or poor sexual performance with a physician. Consultation rates with doctors were considerably higher in Norway (59.6%, OR = 2.25, 95% CI [1.94, 2.60],  $P < 0.001$ ) and Switzerland (44.3%, OR = 1.21, 95% CI [1.05, 1.40],  $P = 0.008$ ). In Poland, just one-quarter of affected men (25.0%, OR = 0.51, 95% CI [0.44, 0.60],  $P < 0.001$ ) had sought medical advice about their condition.

#### Management of ED

Clear variations emerged across the four countries regarding men's engagement with healthcare professionals when addressing erectile dysfunction. Rates of consulting a pharmacist differed markedly between nations (**Figure 4a**). In Germany, 23.6% of participants turned to a pharmacist, compared with 21.5% in Poland. Once adjustments were made for self-reported distress and confirmed ED classification, Norway and Switzerland displayed substantially elevated pharmacist consultation figures: 46.8% in Norway (OR = 2.00, 95% CI [1.72, 2.34],  $P < 0.001$ ) and 34.6% in Switzerland (OR = 1.57, 95% CI [1.33, 1.85],  $P < 0.001$ ). Pharmacists generally directed men with ED symptoms to see a physician for additional assessment, consistent with routine clinical recommendations.



**Figure 4.** Proportion of pharmacy consultations and physician referrals in all four countries: Germany, Norway, Poland, and Switzerland: (a) Proportion of participants who consulted a pharmacist (green) versus those who did not consult a pharmacist (orange), and (b) proportion of participants who the pharmacist referred to a physician (green) versus those who were not referred to a physician (orange) (Germany 2025).

#### Physician referral

Patterns of pharmacist-to-physician referrals also showed notable country-specific differences, mirroring the trends observed for pharmacist consultations (**Figure 4b**). In Germany, 80.7% of those who spoke with a pharmacist were subsequently referred to a doctor. The referral rate dropped to 70.6% in Poland (OR = 0.61, 95% CI [0.43,

0.85],  $P = 0.0039$ ). Higher referral proportions were observed in Switzerland at 85.1% (OR = 1.44, 95% CI [1.02, 2.05],  $P = 0.04$ ) and, especially, in Norway at 93.8% (OR = 3.35, 95% CI [2.30, 4.87],  $P < 0.001$ ).

Non-indicated use of PDE-5Is — meaning use by men who neither self-identified as having ED nor qualified under IIEF-5 criteria — stayed uncommon throughout all four countries. In Germany, merely 18 participants without ED reported taking PDE-5Is. Similar low counts appeared elsewhere: 39 in Norway, 24 in Poland, and 25 in Switzerland.

#### Various channels for acquiring PDE-5Is

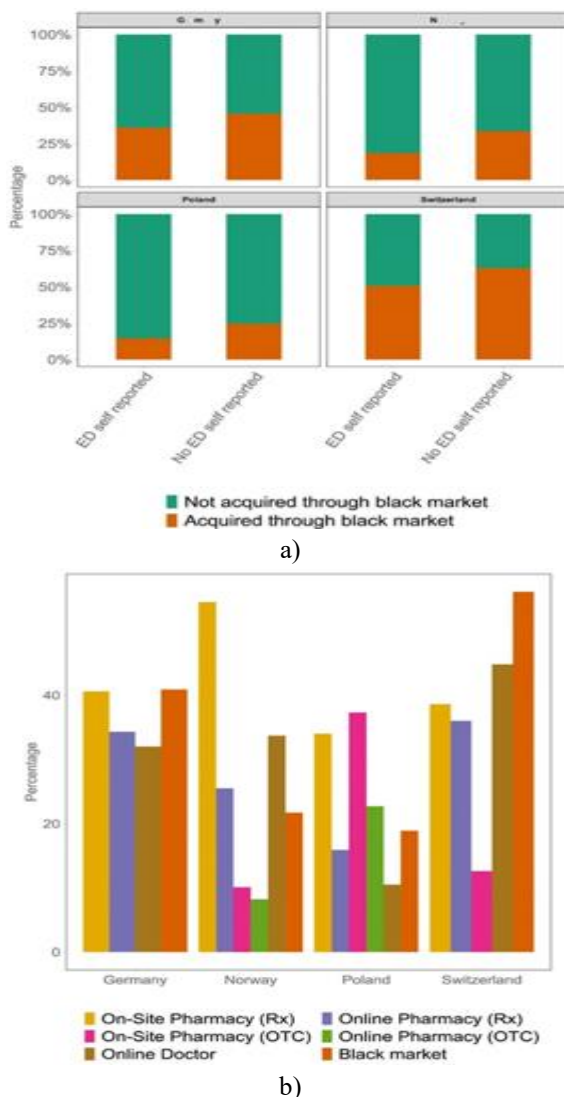
Logistic regression models, adjusted for ED severity and prior doctor visits, demonstrated that self-reporting ED correlated with decreased chances of sourcing PDE-5Is from illicit markets (**Figure 5a**). In a weighted multinomial regression treating legally obtained PDE-5Is as the baseline category, country, age, doctor consultation, and ED severity all emerged as significant factors shaping access patterns. Relative to Germany (40.9%), residents of Norway (21.7%, OR = 0.43, 95% CI: 0.29–0.63,  $P < 0.001$ ) and Poland (18.9%, OR = 0.21, 95% CI: 0.13–0.35,  $P < 0.001$ ) exhibited far lower odds of black market reliance, whereas Swiss participants showed elevated odds (56.1%, OR = 1.65, 95% CI: 1.10–2.46,  $P = 0.01$ ).

Parallel associations held among men who self-reported ED: those in Norway (OR = 0.59, 95% CI: 0.43–0.80,  $P < 0.001$ ) and Poland (OR = 0.39, 95% CI: 0.28–0.56,  $P < 0.001$ ) were less prone to remain without treatment compared with legal users. Age further influenced black market tendencies. Men in the 31–40 years bracket (OR = 1.55, 95% CI: 1.04–2.32,  $P = 0.03$ ) and 41–50 years bracket (OR = 1.83, 95% CI: 1.20–2.79,  $P = 0.005$ ) displayed greater likelihood of illicit sourcing than the 18–30 years group, while older men (51–75 years) did not differ meaningfully.

Having consulted a doctor, it was strongly predicted that legitimate acquisition routes would be available. Men with a prior doctor visit had sharply reduced odds of both black-market purchases (OR = 0.43, 95% CI: 0.31–0.60,  $P < 0.001$ ) and going untreated (OR = 0.14, 95% CI: 0.11–0.18,  $P < 0.001$ ) relative to legal users. ED severity showed no meaningful association with black-market use. However, individuals with mild ED (OR = 0.44, 95% CI: 0.26–0.74,  $P = 0.002$ ), mild-to-moderate ED (OR = 0.36, 95% CI: 0.22–0.60,  $P < 0.001$ ), and moderate ED (OR = 0.43, 95% CI: 0.31–0.60,  $P = 0.005$ ) carried

higher chances of remaining untreated despite acknowledging symptoms.

Further distinctions emerged in the sources men actually relied on to obtain ED medication (**Figure 5b**). Although Norway provided the most straightforward overall access, it also recorded the greatest proportion of prescription-based purchases at physical pharmacies (54.5%). Additional frequent pathways included consultations with online doctors (33.7%) and purchases from online pharmacies (25.5%), ranking second and third, respectively. Roughly 21.7% of men sourced their medication through black market channels, while over-the-counter routes — whether at physical stores or online — accounted for only 10.1% and 8.2% of cases, respectively.



**Figure 5.** Comparative analysis of methods used for acquiring phosphodiesterase-5 inhibitors for erectile

dysfunction treatment across all four countries: (a) Rates of drug acquisition through the black market for self-reported participants with erectile dysfunction (left bar) versus those diagnosed with erectile dysfunction via the International Index of Erectile Function scoring system. Participants who did not acquire phosphodiesterase-5 inhibitors on the black market are shown in green, whereas those who did are shown in orange, and (b) the sources of phosphodiesterase-5 inhibitors: on-site pharmacies with Rx in yellow, on-site pharmacies over the counter in pink, online pharmacies with Rx in purple, online pharmacies over the counter in green, online doctors in brown, and the black market in orange. Each bar represents the percentage of participants using each method in the respective country (Germany 2025). Abbreviations: ED = erectile dysfunction; IIEF-5 = International Index of Erectile Function; OTC = over the counter; PDE-5i = phosphodiesterase-5 inhibitor.

#### *OTC availability of PDE-5Is*

Germany does not permit over-the-counter sales of PDE-5is, keeping this medication class available only by prescription. Consequently, illicit channels emerged as the most common way men obtained treatment for ED (40.9%), followed by traditional pharmacies with a prescription (40.6%), online pharmacies (34.3%), and virtual doctor consultations (32.0%).

Poland displayed a broader mix of acquisition routes. Local pharmacies were the main source, with 34.0% of users receiving the medication with a prescription and 37.3% purchasing it without one. Other pathways included online pharmacies with a prescription (16.2%), online pharmacies without a prescription (22.8%), and underground sources (19.0%). Notably, only 10.8% of those on PDE-5i therapy had turned to online doctors.

In Switzerland, black-market use reached the highest level among the four countries, alongside the greatest reliance on online doctors (44.8%). Meanwhile, formal prescription routes remained comparable to Germany, with 38.6% using physical pharmacies with a prescription and 36.0% obtaining supplies through online pharmacies. Over-the-counter purchases at physical pharmacies accounted for just 12.6% of cases.

This study found that the prevalence of ED, measured using the internationally validated IIEF-5 questionnaire, remained largely consistent across the four countries and across all age groups. Nevertheless, the patient journey

— from recognizing the condition to obtaining and continuing effective treatment — differed markedly between countries. These differences appear closely linked to the varying prescribing requirements for PDE-5Is across nations.

The overall ED prevalence reported here closely aligned with the 61.1% figure from a previous Polish study [17]. By contrast, other research has documented lower rates ranging from 12% to 48% in Finland [18]. Such discrepancies across studies likely stem from variations in research methods and differences in how individuals perceive and report symptoms.

The share of men who self-reported ED was consistently lower than the proportion identified through the IIEF-5 scoring system. Numerous earlier investigations have relied on the IIEF-5 because it is a well-established, validated tool known for its reliability in detecting both the presence and severity of ED. Previous work has demonstrated a strong correlation (Spearman  $r = 0.80$ ) between responses to the questionnaire items and outcomes from independent urological assessments [19], as well as with clinical diagnosis of ED [15].

Notably, self-reporting rates were significantly higher in countries where PDE-5Is do not require a doctor's prescription. This pattern indicates that easier over-the-counter access may foster a more open societal attitude toward discussing and addressing ED. Greater availability of PDE-5Is can meaningfully improve men's wellbeing by increasing the number who actively seek help, encouraging more frequent contact with healthcare professionals, and boosting engagement with pharmacies.

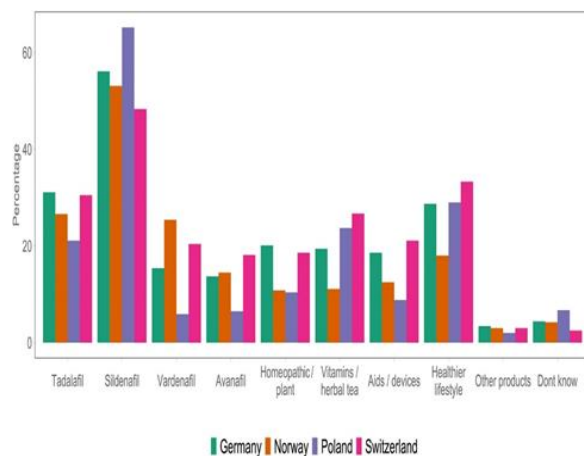
Pharmacist-initiated referrals to physicians for ED concerns occurred more frequently in countries offering OTC access to PDE-5Is. These results suggest that non-prescription availability helps promote appropriate treatment among men who have been identified with ED. In Norway and Poland, where OTC options exist, men showed lower tendencies to use black market sources or to remain untreated, and instead relied more heavily on legitimate channels. In Switzerland, however, the combination of high medication prices, mandatory pharmacist prescriptions, and substantial consultation fees was associated with greater black market activity.

The observation that treatment uptake is higher under OTC conditions than under strict prescription rules is supported not only by cross-country comparisons but also by additional evidence gathered in this survey. When untreated men in the prescription-only reference country

(Germany) were asked about barriers to therapy, both practical obstacles (such as lack of time) and psychological hurdles (reluctance to visit a doctor) were commonly cited. Furthermore, men affected by ED were asked whether they would be more inclined to use PDE-5Is if these were available without prescription and whether black market purchases would decrease as a result. A substantial majority answered yes to both questions.

Market data from countries that have already transitioned to OTC status (e.g., Norway and Ireland) further confirm that non-prescription availability increases overall use of these medications [20]. These observations align with broader healthcare research showing that low-threshold access through pharmacies encourages greater utilization of health services. This effect has been particularly well documented in the context of vaccination programs delivered in pharmacies. The present findings also highlight how time constraints and psychological barriers frequently deter men from seeking care at a doctor's office [21].

Consultations with physicians were strongly associated with the legal acquisition and use of PDE-5Is across all countries, underscoring the value of direct medical contact. Overall, the results indicate that reducing access barriers through OTC availability can help curb unregulated sourcing while expanding access to proper treatment for men who need it (**Figure 6**).



**Figure 6.** Summary of all the products used by the participants across four countries (Germany 2025).

The findings indicate that ED is linked to cardiovascular diseases; therefore, patients should be encouraged to consult a physician to reduce the risk of cardiovascular complications [13, 22]. In addition, pharmacists should

begin by asking about cardiovascular health, current medications, and any other existing medical conditions. They should advise men purchasing PDE-5Is to schedule a follow-up visit with their doctor within 6 months, or earlier if needed, to properly evaluate any underlying health issues [23].

This study showed that in all four countries, the majority of men intending to buy a PDE-5i from a pharmacy were recommended to see a doctor (DE: 81%; NO: 94%; PL: 71%; CH: 85%). This pattern held regardless of the regulatory framework — whether a doctor's prescription was required, as in DE (81%), or not required, as in NO (94%), CH (85%), and PL (71%). In many European countries, pharmacies enjoy high levels of public trust, and their advice is often followed [24, 25]. This suggests that even when PDE-5Is can be obtained without a prescription, men with ED still tend to heed medical guidance and consult a physician.

Supporting this observation, Norway — where PDE-5Is are available over the counter with minimal barriers — recorded a higher combined rate of PDE-5i prescriptions issued by doctors and dispensed at pharmacies (80%) compared with Germany and the other reference countries. A prior analysis examined potential shifts in the features of Individual Case Safety Reports, including the seriousness or outcomes of adverse events linked to tadalafil, following its transition from prescription-only to OTC status. The analysis found no increase in reported adverse events or any new safety concerns associated with the switch to OTC availability [26].

Another study evaluating the benefits and risks of making tadalafil available without a prescription in Germany concluded that clinical experts agreed on the minimal additional risks, if any, resulting from the change. There was broad consensus that any such incremental risks would have limited clinical significance, could be readily managed, and were far outweighed by the potential benefits [22].

Difficulties in obtaining proper treatment for ED have prompted many men to turn to unauthorized sources of PDE-5is, thereby bypassing formal healthcare pathways [11]. As early as 2010, research estimated that around 6 million men across Europe were acquiring PDE-5Is outside the regulated healthcare system [27]. The present data align with the existing literature, confirming that black-market channels remain a notable source of PDE-5is, especially in countries where the medication is not available over the counter. Therefore, approving PDE-5Is as OTC medicines appears essential to reduce reliance on

illegal sources and to provide safer, more accessible treatment for affected patients.

From a public health standpoint, the role of illicit black-market channels is considerably smaller in countries that do not mandate prescriptions. In Germany (prescription-only setting), more than one in three participants (40.9%) reported obtaining PDE-5Is through illegal channels. In contrast, black market use was markedly lower in Poland and Norway (OTC settings). However, Switzerland presented a distinct pattern: despite no prescription requirement, black-market use remained notably high. This may be explained by the high healthcare costs in Switzerland, where obtaining PDE-5Is from a pharmacist incurs a consultation fee in addition to the already high medication price. As a result, many men in Switzerland appear to opt for cheaper alternatives available on the black market.

Non-indicated use of PDE-5Is — that is, use by men without ED — was uncommon in all four countries. One of the main arguments for maintaining prescription requirements is to prevent use by individuals who do not have the condition. Yet the survey data provide only limited support for this concern. In Germany (prescription-only), just 18 out of 1,007 men without ED reported using these drugs, and the rest had received a doctor's prescription. Even in countries offering OTC access, non-indicated use remained rare (NO: 39/918; PL: 24/822; CH: 25/828). Furthermore, earlier research has indicated that the risks associated with PDE-5i use in the absence of ED are relatively low [19].

#### *Limitations*

The study has certain limitations, as it included data from only a small number of countries with diverse cultural backgrounds and healthcare system structures. These differences may have contributed to distinct treatment-seeking behaviors and varying impacts on quality of life (QoL). In questionnaire-based research, verifying the accuracy of participants' responses can be difficult. The study acknowledged the possibility of bias arising from men underreporting their ED symptoms, while it is highly improbable that men without the condition would falsely claim to have it. Respondents in this survey are more likely to portray their sexual performance more favorably than it actually is. As a result, the prevalence and severity figures obtained here may underestimate the true burden of ED. Given these conservative estimates, the actual number of untreated men could be even higher. Strategies are therefore needed to minimize such

uncertainty, enhance the reliability of responses, ensure more accurate data representation, and reduce potential distortions. The use of a digital platform may have further contributed to lowering the officially reported statistics. Additionally, factors such as access to digital devices, internet proficiency, and the characteristics of online engagement could have affected participation levels and response quality, thereby influencing the overall dataset. The above considerations highlight the pressing need to transition PDE-5Is from prescription-only to over-the-counter status.

### Conclusion

ED is a widespread condition among men that carries a considerable disease burden. Beyond its direct impact on male sexual health, it is closely associated with serious underlying disorders such as coronary heart disease and diabetes. Despite its high prevalence, ED remains a sensitive topic, which often leads to under-reporting and reluctance to seek help, leaving many men untreated. In light of this, the present study examined how differing regulatory approaches to prescription requirements affect patient pathways and the utilization of PDE-5is.

Comparison of data from four countries indicates that easier access without a doctor's prescription resulted in a higher proportion of men using PDE-5is. Furthermore, reliance on illegal black-market sources was markedly lower among participants in countries with OTC availability (NO, PL) than in Germany, where medicines remain prescription-only, or in Switzerland, where healthcare costs are elevated. In an OTC environment, more men with ED consulted a pharmacist, and the majority of these men were advised to see a doctor for further medical evaluation. Given the strong public trust in pharmacists' recommendations, this setting offers a valuable opportunity to identify early potential underlying conditions (e.g., cardiovascular diseases) that may be contributing to ED.

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