# **Erectile dysfunction**

A handbook for pharmacists on managing symptoms and supporting self-care

PEOPLE-CENTRED CARE

**FIP Development Goals** 

## **Erectile dysfunction**

FIP Practice Transformation Programme on NCDs



2025



## Colophon

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# **Executive summary**

Erectile dysfunction (ED) is the most common male sexual dysfunction, affecting millions worldwide. It is defined as the persistent inability to achieve and maintain an erection sufficient for satisfactory sexual performance. This condition has significant physical, emotional and psychosocial implications, affecting the well-being of both the affected individuals and their sexual partners.

The prevalence of ED is known to increase with age and is associated with a number of factors such as comorbidities, lifestyle choices, and physical and psychological problems. In addition, ED may be a marker for more serious underlying health conditions, such as cardiovascular disease and diabetes. If untreated or poorly managed, ED can precede these conditions as well as contribute to depression and relationship difficulties, further affecting the patient's overall well-being. In this context, pharmacists are ideally placed to bridge the gap in care by providing evidence-based, accessible, cost-effective support. Community pharmacies in particular offer a convenient setting for screening and early detection, such as through point-of-care testing, as well as for delivering pharmacological treatments and lifestyle interventions, including tobacco cessation, stress management, weight control, healthy eating, and physical activity. These interventions can significantly improve patient outcomes and help address the wider health consequences of ED.

Pharmacists play a critical role in the management of ED by providing ongoing support and expert advice to patients, promoting health education and addressing the social and psychological barriers associated with treatment. Their expertise in medicines and counselling enables them to identify risk factors, advise on treatment options, and promote adherence to treatment plans, all within a people-centred approach.

This handbook has been developed as a practical and comprehensive tool for pharmacists in patient-facing roles, offering evidence-based guidance on both pharmacological and non-pharmacological approaches to supporting patients with ED. It covers topics from understanding the condition to assessment, diagnosis, treatment strategies and psychosocial support. The aim is to enable pharmacists to take a proactive role in helping patients to make informed decisions about their treatment and health. Effective management of ED could involve a combination of approaches, including pharmacotherapy, lifestyle changes, psychological counselling, and the use of medical devices.

This handbook further emphasises the importance of interprofessional collaboration, which is essential for the successful management of ED. Pharmacists are encouraged to collaborate closely with physicians, psychologists and other healthcare professionals to deliver holistic and effective care. It also addresses the professional and ethical responsibilities of the pharmacist, particularly in addressing challenges related to access, misuse and misunderstanding of ED medications. As part of these responsibilities, pharmacists should also play a key role in protecting patients from the growing market of substandard, falsified and unregulated ED treatments (as described in Chapter 7).

With the guidance and strategies outlined in this handbook, pharmacists are well placed to play a key role in the management of ED, helping to reduce stigma and provide accessible, effective care for men affected by this condition. By adopting a people-centred approach, pharmacists can improve the quality of life for those affected by ED by providing treatments that meet their needs and preferences, while helping to reduce the global burden of erectile dysfunction.

## Note to the reader

In this publication, the term "men" is used in the context of erectile dysfunction (ED) as a medical condition primarily affecting individuals assigned male at birth. This terminology reflects the prevailing clinical definitions currently used in practice. However, we acknowledge that this definition may rest on heteronormative assumptions and may not fully represent the experiences or needs of individuals who identify as transgender, nonbinary, or gender diverse. Further efforts are needed to improve inclusivity in the understanding and management of ED across all populations.

References to "men and their partners" refers to sexual partners, regardless of gender or sexual orientation.

The term "patients" is used throughout this publication to refer to individuals experiencing or at risk of experiencing ED.

Also, FIP acknowledges that the regulatory status of medicines used to treat erectile dysfunction (such as sildenafil and tadalafil) varies across countries. In some settings, these medicines require a prescription from a physician, while in others they may be supplied without a prescription or are prescribed directly by pharmacists. As this resource is intended for a global audience, the guidance provided is general and should be interpreted in accordance with national laws and professional regulations in those nations and territories.

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# Foreword by the FIP President

In 2021, FIP launched its <u>practice transformation programme on non-communicable diseases</u> (NCDs), designed to provide tools and strategic support to FIP member organisations to develop and implement pharmacy services that can have a sustained positive impact in the prevention, screening, management, and treatment optimisation of NCDs for improved patient outcomes and health systems efficiency and sustainability. As part of this programme, FIP developed a series of practice support handbooks, knowledge and skills guides, and other resources addressing the five major NCD areas (<u>cancer</u>, <u>cardiovascular diseases</u>, <u>chronic respiratory diseases</u>, <u>diabetes</u>, and <u>mental health</u>) as well as risk factors such as <u>tobacco use</u>.

Building on this foundation, this new handbook focuses on erectile dysfunction (ED), a common yet widely underestimated condition with significant implications for men's health and well-being. Recognising that ED can be an early indicator of wider health problems, this publication has been carefully crafted to help pharmacists fill critical gaps in care. By bringing together the latest evidence, expert guidance and practical tools, it empowers community pharmacists to effectively identify, manage and support patients experiencing

As accessible and trusted healthcare professionals, pharmacists are uniquely positioned to provide confidential advice, facilitate early detection, and implement holistic care pathways. This publication highlights the value of integrating both pharmacological and non-pharmacological strategies into patient care through targeted counselling and interprofessional collaboration. Pharmacists can contribute in many effective ways to support men with ED, including:

- Providing convenient and timely access to healthcare and treatment
- Ensuring the safe provision of pharmacological treatments for ED, including over-the-counter options in countries where regulations allow, through comprehensive patient assessment
- · Providing screening services that identify risk factors and underlying health problems at an early stage
- Providing opportunities to initiate conversations about sensitive health issues
- Encouraging self-care by supporting lifestyle changes such as weight management, physical activity, and tobacco cessation
- Reviewing patients' medications to ensure appropriate use and minimise adverse effects
- Providing advice on the safe and effective use of treatments, including guidance on side effects, interactions and nonpharmacological interventions.

Pharmacists are often the first healthcare professionals that men turn to for advice, making them a crucial point of access for identifying not only erectile dysfunction, but also the underlying health conditions that may be contributing to it. By encouraging open, non-judgmental discussions, they can help break down the stigma surrounding ED and ensure that men get the support they need, while also enabling early detection of serious comorbidities such as cardiovascular disease or diabetes. Through timely referral and people-centred care, pharmacists have an important role to play in improving both individual and public health outcomes.

This handbook provides pharmacists with the knowledge and practical strategies to strengthen their role in ED management, from recognising risk factors and identifying red flags for referral to understanding the nuances of pharmacological and non-pharmacological treatments. By equipping pharmacists with the tools to provide people-centred care and promote early intervention, this resource reaffirms FIP's commitment to advancing pharmacy practice and improving health outcomes in men's health worldwide. We hope it will serve as a valuable guide, encouraging you to integrate these approaches into your daily practice and play an active role in improving the care and support available to men affected by this condition.

Forward with Pharmacy, Forward with FIP

Paul Sinclair President

International Pharmaceutical Federation (FIP)

# **Foreword by Dr Gerald Brock**

I am the Past-President of the International Society for Sexual Medicine, Past-President of the Canadian Urological Association, and a research-based urologist who has led a basic research team investigating the erectile and sexual dysfunction concerns of men for three decades. The importance of this therapeutic area is in its high prevalence, important negative impact on quality of life, and its role as an early warning sign of generalised vascular disease and cardiac health. Some estimates place the incidence of erectile dysfunction at more than 50% of men aged over 50. Men who develop vascular-based erectile dysfunction will frequently present with sexual problems 30 months prior to their first cardiac event.

The authors of this handbook should be commended for this timely, well-balanced and comprehensive tool directed at pharmacists.

The evolving field of men's sexual health was turbocharged almost 30 years ago with the approval of sildenafil. The development of an oral pill able to selectively target the penile vasculature provided men and their partners with a safe and effective means to restore physical intimacy. This transformative discovery placed the pharmacist at the centre of the treatment team, with many men asking their local pharmacist for advice, their help in choosing a treatment and in many cases led to the pharmacist making a diagnosis. The field has continued to develop, with expanded outreach to the lay public through media adverts on TV, radio, print and the internet.

The overall credibility of many of these sources of information remains dubious and in some cases are clearly simply promotional, without a basis in science to support their claims.

It is in that environment, having a well-informed healthcare professional in the pharmacy, able to provide evidence-based advice to men and their partners, that treatment optimisation can be reached.

This handbook seeks to address a wide range of topics on sexual function and provides the pharmacist with a level of detail that should equip them with the skills and knowledge to support their patients.

In many parts of the world, access to well-informed physicians with sexual health knowledge is lacking. The ability to provide that care at the local pharmacy is cost-effective. The critical information contained within this handbook should result in improved patient and partner outcomes.

The authors and others integral to the creation of this handbook should be congratulated. I am certain that many tens of thousands of men and their partners will benefit from the care that pharmacists provide using the information contained within it.

Dr Gerald Brock Professor Emeritus of Surgery, Division of Urology, Western University Past-President, International Society for Sexual Medicine Medical Director of Advanced Medical & Surgical Group

# 1 Role of pharmacists in supporting patients with erectile dysfunction

## 1.1 A people-centred approach to erectile dysfunction

A people-centred approach is essential in the management of erectile dysfunction, which can have a significant impact on men and their partners' quality of life and psychological well-being. This model of care emphasises the importance of understanding an individual's needs, preferences, and values, and promotes a collaborative partnership between healthcare professionals and patients, their families and carers. This approach empowers patients to take an active role in managing their symptoms and long-term health decisions.<sup>1</sup>

ED can be caused by a combination of physical and psychological factors, including chronic diseases, neurological conditions, lifestyle-related risks, and emotional concerns. A biopsychosocial approach to the treatment of ED is essential, as it considers not only biological factors, such as underlying medical conditions, but also psychological and social aspects, including emotional well-being, relationship dynamics and lifestyle influences. This comprehensive approach helps to assess and plan treatment more effectively.<sup>2</sup>

Effective communication, underpinned by openness and empathy, is key to building trust and encouraging people to discuss their concerns and expectations without fear of judgement. It is essential that the pharmacist is empathetic, caring and sensitive to ensure that patients feel supported. Additionally, pharmacists should ensure that care is tailored to the individual, promoting their comfort in discussing sensitive issues and actively engaging in self-care practices. In the context of ED, self-care practices might include lifestyle modifications, such as improving diet, increasing physical activity, and active stress management approaches, which can support treatment adherence and improve clinical outcomes. By involving people in treatment decisions, pharmacists can help enhance adherence and clinical outcomes, making patients feel empowered and supported throughout their care journey.<sup>3</sup>

Pharmacists can further support patients and their partners by creating a private and welcoming environment for discussing ED. Establishing confidential consultation areas and using empathetic communication techniques will help minimise embarrassment and encourage individuals to seek the support they need.<sup>3</sup>

Chapter 6 lays out in more detail how ED can be managed in the pharmacy, taking a people-centred approach.

## 1.2 Why pharmacists are key in managing erectile dysfunction

Pharmacists play a crucial role in the management of ED as accessible and trusted healthcare professionals, often acting as the first point of contact for men experiencing this condition.<sup>4</sup> Their position within the community enables them to provide advice, education, and support in a discreet and professional environment, which is particularly important given the stigma associated with ED that may deter individuals from seeking medical advice. Beyond facilitating access to effective treatment (both pharmacological and non-pharmacological, such as lifestyle changes), pharmacists can identify potential underlying health problems, such as cardiovascular disease or diabetes, during consultations and refer individuals to the most appropriate healthcare professional when necessary.<sup>5</sup>

As medicine experts, pharmacists are well placed to provide information about the treatment options available for ED. Their role has become increasingly important as phosphodiesterase type 5 inhibitors (PDE5Is), such as sildenafil and tadalafil, have been reclassified in some countries as non-prescription medicines available only from a pharmacy and under the supervision of a pharmacist.<sup>6</sup> This change has increased pharmacists' responsibilities, requiring them to assess the potential causes of ED, determine whether treatment is appropriate, screen for contraindications and other risks, discuss potential side effects and medicine interactions, and provide guidance on proper use to ensure safe and effective use.<sup>6-8</sup>

A UK study showed that, following the reclassification of sildenafil as a pharmacy medicine, men using sildenafil had more frequent healthcare visits, including consultations with both pharmacists and healthcare providers such as physicians or nurse practitioners. <sup>6</sup> Greater engagement with the healthcare system over time can increase the likelihood

of diagnosing and treating both ED and underlying long-term conditions. The results also highlight the need for more frequent and proactive involvement of community pharmacists in the preventative care of men with ED.<sup>6</sup>

In addition to their expertise in medicines, pharmacists promote self-care by encouraging lifestyle changes that support erectile function. These include tobacco cessation, reducing alcohol consumption, increasing physical activity, adopting a healthier diet, managing weight and stress, improving sleep hygiene, and supporting mental well-being. Such changes not only enhance overall health but also have a direct positive impact on erectile function.<sup>5</sup>

The role of pharmacists extends to raising awareness and reducing the stigma surrounding ED. Many individuals are reluctant to seek help due to embarrassment, but pharmacists can create a supportive, non-judgmental environment that encourages open and honest dialogue. By normalising discussions about ED, pharmacists not only help individuals feel more comfortable addressing their concerns but also empower them to seek appropriate care and explore treatment options.<sup>3</sup>

In addition to providing guidance and support, pharmacists contribute significantly to the early detection and ongoing management of ED. They are well-positioned to identify individuals who may be at risk due to underlying medical conditions such as diabetes, hypertension or cardiovascular disease—conditions for which ED may be an early warning sign. By identifying these risks, pharmacists can facilitate timely referrals to healthcare providers and enhance interprofessional collaboration. Through this proactive, people-centred approach, pharmacists help not only to manage ED but also to uncover and address broader health issues, ultimately improving patient outcomes and promoting long-term well-being.<sup>4, 5</sup>

The importance of pharmacists in ED management is further highlighted by the EPIFARM study, conducted in 574 community pharmacies in Spain.<sup>9</sup> The study found that 60% of men without a prescription had their first discussion about ED with a pharmacist, and among those who had previously sought medical advice, half had initially consulted a pharmacist. Additionally, 40% of men who later obtained a prescription had first spoken to a pharmacist before seeing a physician. These findings highlight the role of the pharmacist in initiating conversations about ED, guiding patients to appropriate treatment and facilitating early detection of comorbidities.<sup>9</sup>

## 1.3 Pharmacy-based services for erectile dysfunction

Pharmacists offer a range of services that can support individuals with ED, providing a confidential and accessible setting for counselling and management. The availability of these services may vary depending on national regulations and jurisdictional frameworks.

Key pharmacy-based services include:

- Screening and risk assessment: Many pharmacies provide health screening services to evaluate cardiovascular
  risk factors such as blood pressure, blood glucose, and cholesterol levels, which are often linked to ED.
  Pharmacists can conduct these screenings to help identify potential underlying causes and guide individuals
  toward further medical evaluation if needed.<sup>10</sup>
- **Pharmacist-initiated medicines**: In some countries, pharmacists are authorised to prescribe certain ED medications, such as sildenafil and tadalafil. This is typically done following a structured consultation to ensure the safety and appropriateness of therapy for the individuals.<sup>6-8</sup>
- Medicines use review (MUR): Pharmacists can review patients' medication regimens, ensure they understand how to take their ED treatments correctly, and address concerns about side effects or potential medicine interactions.<sup>11</sup> During this process, pharmacists can also identify medications being used for other conditions—such as antidepressants, antihypertensives, or even certain recreational drugs—that could be contributing to ED. By recognising these contributing factors, pharmacists can initiate meaningful conversations with patients and help explore appropriate solutions, including possible adjustments to therapy in collaboration with other healthcare professionals.
- **Tobacco cessation support:** As tobacco use is a known risk factor for ED, pharmacists can provide tobacco cessation services, including nicotine replacement therapy and behavioural counselling.<sup>12</sup>

- Weight management and lifestyle changes: Pharmacists can support individuals with tailored lifestyle advice, including weight management services, promotion of physical activity, stress management and advice on dietary changes.<sup>13</sup>
- Referral and interprofessional collaboration: Pharmacists can identify cases where medical intervention is
  required and refer individuals to general practitioners or specialists for further assessment of underlying
  conditions contributing to ED. Establishing strong referral pathways ensures that the person receives
  comprehensive care beyond the pharmacy setting.<sup>4</sup>

Pharmacists can also enhance accessibility by implementing structured follow-up services, monitoring treatment progress, and adjusting care plans as needed. Regular follow-ups help assess the efficacy of treatment and address any concerns or side effects experienced by individuals.

In summary, pharmacists provide an integrated approach to managing erectile dysfunction. Their services may include screening and risk assessment, lifestyle advice, medicines use review, dispensing prescribed medicines, and, where permitted by national legislation, prescribing and dispensing newly classified medications for ED. The addition of structured follow-up services ensures continuous monitoring of treatment progress and patient concerns, while collaboration with healthcare professionals further enhances patient care. This comprehensive support improves both treatment outcomes and the overall quality of life for those affected by ED. Throughout this handbook, examples will be provided to illustrate how pharmacists can deliver these services effectively in the community setting.

# 2 Understanding erectile dysfunction

## 2.1 Definitions and classifications

Erectile dysfunction is the most common sexual dysfunction among men and a significant health problem affecting millions of men worldwide. 14, 15 Defined as the persistent inability to achieve and maintain an erection sufficient for satisfactory sexual performance, ED can negatively impact psychosocial well-being and significantly reduce the quality of life of both patients and their partners. 16 The aetiology of ED is complex and multifactorial and is commonly classified into three categories: organic, psychogenic and mixed. 16 However, this classification should be used with caution, as most cases have a mixed aetiology. Therefore, the terms "primary organic" or "primary psychogenic" are often preferred. While primary organic ED refers to cases caused mainly by physical or physiological factors, primary psychogenic ED is mainly associated with psychological or emotional causes. 16

## 2.2 The burden of erectile dysfunction

#### 2.2.1 Prevalence

Erectile dysfunction (ED) is a prevalent and multifaceted condition that predominantly affects men over 40, with increasing prevalence with age. While not every man in this age group experiences ED, the likelihood of developing the condition rises significantly with advancing age, making it an important health concern globally. 14, 17, 18

The prevalence of ED varies widely due to differences in study populations, definitions, and assessment methods. <sup>14, 19</sup> Studies in Brazil found prevalence rates of 35% among men aged 18-40 and 45.9% among men aged 40-70. Global estimates range from 3% to 76.5%, with the highest rates reported in Europe (10-76.5%), Asia (8-71.2%), Oceania (40.3-60.69%), Africa (24-58.9%), and North America (20.7-57.8%), while the lowest prevalence was found in South America (14-55.2%). <sup>14</sup>

Geographical differences in the prevalence of ED are influenced by a combination of genetic, environmental and lifestyle factors. Major ED risk factors include ageing, comorbidities (e.g., diabetes, cardiovascular diseases, obesity, prostate cancer, depression and anxiety treatment), heavy alcohol and tobacco consumption, as well as socioeconomic factors such as unemployment and low income. Single, separated, or divorced men are also at higher risk. Additionally, cultural differences in the perception of ED, combined with the sensitive nature of the condition, may influence how it is reported, potentially contributing to variations in prevalence data.<sup>14</sup>

Epidemiological studies highlight the increasing prevalence of ED, which is expected to affect 322 million men worldwide by 2025, an increase of 111% since 1995. <sup>14, 18</sup> Despite this, ED remains underdiagnosed and undertreated, <sup>20</sup> often due to stigma, lack of awareness and limited access to healthcare services.

The burden of untreated or poorly managed ED goes beyond sexual health and its impact on intimacy, extending to overall well-being and health. It can precede other serious conditions such as cardiovascular diseases or diabetes, <sup>21</sup> and can contribute to depression and relationship difficulties. <sup>16</sup> In this context, pharmacists are ideally placed to bridge the gap in care by providing accessible, cost-effective support that includes early detection, pharmacological treatment and lifestyle interventions. Community pharmacies offer an accessible setting where men can receive advice, effective medication and support with health-promoting changes such as tobacco cessation, weight management, and healthy eating habits. Pharmacists can also conduct point-of-care testing (POCT) to help identify and manage underlying health conditions. <sup>4-6</sup>, <sup>9</sup>

## 2.2.2 Impact on quality of life

ED significantly impacts the quality of life of affected men and their partners, affecting physical, psychological, social, and emotional well-being. This broad impact extends to various aspects of daily life, affecting not only the individual's health but also their relationships, work productivity, and overall life satisfaction.<sup>22</sup> The following key areas are particularly affected by ED:

Physical impact: Men with ED often experience lower physical health scores compared to those without ED.<sup>22</sup>

- Psychological impact: ED can lead to low self-esteem, feelings of guilt, lack of confidence, failure, shame and
  emotional distress. It is strongly associated with an increased risk of depression, anxiety, anger and frustration.
  The emotional toll of ED is particularly significant, as men may feel that they are letting their partner down,
  which further affects their mental well-being.<sup>22</sup>
- Social and relationship impact: ED can affect relationships by reducing sexual satisfaction, frequency of sexual
  activity, and communication between partners. Feelings of decreased desirability and masculinity can lead to
  emotional distress for both men and their partners. Female partners of men with ED also report lower
  satisfaction with their sexual relationships and overall quality of life.<sup>22</sup>
- Work and economic impact: ED can lead to increased absenteeism and reduced productivity at work, placing an economic burden on employers and society.<sup>22</sup>
- Overall quality of life: Overall, studies demonstrate that men with ED experience a deterioration in psychological, social, and physical well-being compared to those without ED, and are often dissatisfied with their overall quality of life. The impact is even more pronounced in those with ED and comorbidities.

Although ED is not life-threatening in itself, it has a significant impact on the quality of life of men and their partners. There is a clear need for improved management and support to address both the physical and emotional challenges of ED. Pharmacists have an important role to play in providing accessible care by starting conversations, screening, offering guidance on treatment options, providing emotional support, and referring men to other healthcare professionals when needed, to help alleviate the burden of this condition. Practical guidance on how to deliver these aspects of care is provided throughout this handbook.

#### 2.2.3 Complications and prognosis

The prognosis for ED depends largely on the underlying cause.<sup>19</sup> In cases where modifiable risk factors, such as tobacco use and physical inactivity contribute to ED, addressing these lifestyle factors can significantly improve erectile function. In some cases, medicines used to manage other health conditions may contribute to or worsen ED; identifying these and considering alternative treatments can help improve outcomes. Similarly, if there is a problem with low testosterone or thyroid hormone imbalance, correcting the imbalance can resolve erectile problems. However, for men with ED associated with chronic conditions where there are microvascular changes such as those seen with diabetes mellitus and cardiovascular disease, or neurological disorders such as Parkinson's disease (PD), spinal cord injury or anxiety, the condition often proves more persistent and challenging to manage and would involve input from other members of the wider healthcare team.<sup>17</sup>

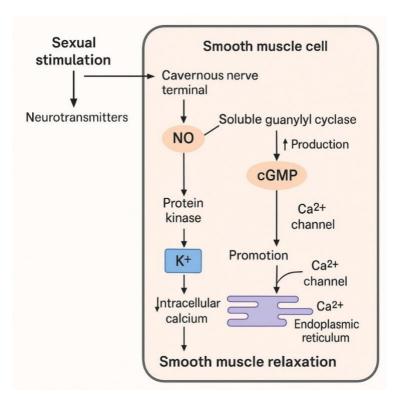
Complications of untreated ED can include worsening cardiovascular health, as it is often associated with conditions such as hypertension and atherosclerosis. It can also contribute to mental health issues, such as anxiety and depression. In some cases, persistent ED can strain relationships, leading to social withdrawal and reduced quality of life.<sup>23</sup>

Effective treatment, including pharmacological treatments and lifestyle changes, can improve both erectile function and overall well-being. Pharmacists have a key role to play in providing accessible care and helping to manage both the physical and emotional challenges of ED.

## 2.3 Pathophysiology

Erection relies on the success of a number of complex neurovascular events, and disruption to any of these events can result in erectile dysfunction. Initially, sexual stimulation, whether psychogenic or reflexogenic, activates the parasympathetic nervous system. This activation leads to the release of nitric oxide (NO) from endothelial cells and non-adrenergic, non-cholinergic (NANC) neurons within the corpora cavernosa. NO stimulates guanylate cyclase, which increases cyclic guanosine monophosphate (cGMP) levels in the smooth muscle cells of the corpora cavernosa. Elevated cGMP induces relaxation of the smooth muscle and arterial dilation, resulting in increased blood flow into the cavernosal sinusoids. This expansion compresses the subtunical venous plexus against the tunica albuginea, effectively reducing venous outflow and maintaining penile rigidity. The erection is sustained as long as cGMP levels remain elevated, with this process regulated by phosphodiesterase type 5 (PDE5), which degrades cGMP to terminate the erection (see Figure 1). Detumescence occurs when sympathetic activity predominates, leading to the contraction of cavernosal smooth muscle, reduced arterial inflow, and restoration of venous drainage.<sup>17</sup>

Figure 1 – Physiology of erectile function



AI-generated ChatGPT4o

Disruptions at any stage of this process, such as impaired nitric oxide release, reduced cGMP production, or excessive PDE5 activity, can result in erectile dysfunction. Figure 2 and Table 1 illustrate the mechanisms through which various risk factors contribute to its development.

Figure 2 – Erectile dysfunction development<sup>13</sup>

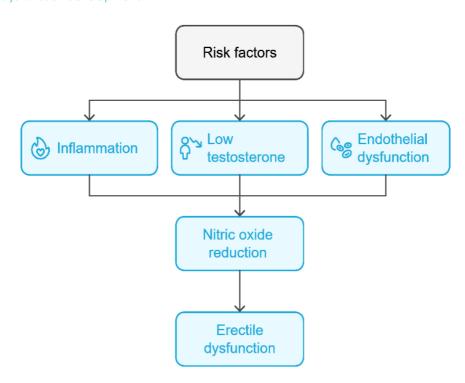


Table 1 – Risk factors and their underlying mechanisms linked to erectile dysfunction<sup>13</sup>

Risk factors	Mechanism
Metabolic syndrome	Endothelial dysfunction and low nitric oxide synthase regulation
Benign prostatic hyperplasia	Probable decrease of nitric oxide in the penis, bladder, and prostate
Cardiovascular disease	Endothelial dysfunction in the vasculature of the penis
Tobacco use	Endothelial dysfunction associated with atherosclerosis
Depression, social problems, or stressful relationship	Unknown
Diabetes mellitus	Endothelial dysfunction, vasculopathy, and neuropathy
Hypogonadism	Low androgen levels that lead to increased apoptosis of endothelial cells and smooth muscle cells

## 2.4 Aetiology

Erectile dysfunction can arise from a wide variety of underlying medical and physiological conditions. The aetiology of ED is complex, involving organic (vascular, neuronal, anatomical, hormonal, metabolic), psychogenic, and iatrogenic causes as outlined in Table 2.<sup>16, 19</sup> The main mechanisms contributing to ED are as follows:

- Vascular causes: ED is often associated with poor blood flow to the penis, which is necessary to achieve and
  maintain an erection. Conditions such as atherosclerosis, diabetes and hypertension cause narrowing and
  hardening of the blood vessels, reducing blood flow to the penis and resulting in ED. These vascular conditions
  are among the most common causes of ED.<sup>16, 19</sup>
- **Neurogenic causes:** The nervous system plays a crucial role in initiating and maintaining an erection. Neurological conditions such as Parkinson's disease, multiple sclerosis and spinal cord injury can affect nerve function and lead to ED. In addition, surgery, especially prostate surgery, can cause nerve damage that affects erectile function. 16, 19
- Anatomical causes: Several anatomical conditions can contribute to ED by affecting the structure and function of the penis. Peyronie's disease, characterised by the formation of fibrous plaques in the penile tissue, can cause curvature, pain and difficulty in achieving or maintaining an erection.<sup>24</sup> Congenital abnormalities such as congenital curvature of the penis, micropenis, hypospadias and epispadias can also affect normal erectile function. Phimosis, a condition in which the foreskin is too tight to retract, can cause discomfort and interfere with erections.<sup>19</sup> In addition, penile cancer and surgery for prostate or bladder cancer can cause structural changes that affect erectile function.<sup>24</sup>
- Hormonal causes: Hormonal imbalances, particularly low testosterone levels, have been identified as a significant factor in ED. Testosterone is essential for sexual desire and erectile function, and conditions such as hypogonadism can contribute to ED. Other hormonal disorders, such as thyroid disorder or hyperprolactinaemia, can also contribute to ED.<sup>25</sup> Additionally, metabolic conditions, including type 1 and type 2 diabetes mellitus and metabolic syndrome, can exacerbate ED due to their effects on vascular health and hormonal balance.<sup>16, 19</sup>
- **latrogenic causes:** Certain medications and medical treatments can contribute to ED as an adverse effect by interfering with vascular, neurological, or hormonal mechanisms involved in erectile function. Antihypertensive agents, particularly beta-blockers and diuretics, can affect penile blood flow, while selective serotonin reuptake inhibitors (SSRIs) and other antidepressants can disrupt neurotransmitter balance, affecting sexual response. Anxiolytics, antipsychotics and certain hormone therapies can also contribute to ED.<sup>16, 19, 25</sup> For a more detailed list of medications associated with ED, see Table 2.

• **Psychogenic causes:** Psychogenic ED can be categorised into generalised and situational types. Generalised causes can include a reduced ability to achieve sexual arousal or difficulties with sexual intimacy. On the other hand, situational ED can result from problems with a partner or performance, including problems within relationships (whether marital, extramarital or with a new partner). Psychological factors such as stress, depression, anxiety, post-traumatic stress disorder and psychosis are also important contributors to ED. One key factor—performance anxiety—can lead to a reinforcing cycle that exacerbates erectile difficulties.

Table 2 – Causes associated with erectile dysfunction<sup>16, 19, 24</sup>

Causes	Examples		
Pathological causes	Pathological causes		
Vascular-related	<ul> <li>Cardiovascular disease</li> <li>Hypertension</li> <li>Atherosclerosis</li> <li>Peripheral vascular disease</li> <li>Hyperlipidaemia</li> <li>Myocardial infarction</li> <li>Type 1 and 2 diabetes mellitus</li> <li>Metabolic syndrome</li> <li>Obesity</li> <li>Hyperhomocysteinemia</li> <li>Vascular injury from radiation therapy</li> <li>Vascular injury from prostate cancer treatment</li> <li>Blood vessel and nerve trauma (e.g., from long-distance bicycle riding)</li> <li>Medications for the treatment of vascular disease</li> <li>Recreational habits (e.g., tobacco consumption)</li> </ul>		
Neurogenic-related (central system causes)	<ul> <li>Epilepsy</li> <li>Stroke</li> <li>Multiple sclerosis</li> <li>Parkinson's disease</li> <li>Guillain-Barré syndrome</li> <li>Alzheimer's disease</li> <li>Spinal cord trauma or diseases</li> <li>Central nervous system tumours</li> </ul>		
Neurogenic (peripheral causes)	<ul> <li>Type 1 and 2 diabetes mellitus</li> <li>Chronic kidney disease</li> <li>Chronic liver disease</li> <li>Polyneuropathy</li> <li>Major surgery of the pelvis or retroperitoneum</li> <li>Radiotherapy (pelvis or retroperitoneum)</li> <li>Urethral surgery</li> </ul>		
Anatomical or structural causes	<ul> <li>Peyronie's disease</li> <li>Penile cancer</li> <li>Prostate cancer</li> <li>Congenital curvature of the penis</li> <li>Micropenis</li> <li>Hypospadias</li> <li>Epispadias</li> </ul>		

Causes	Examples
	<ul><li>Phimosis</li><li>Priapism</li></ul>
Hormonal/ endocrine conditions	<ul> <li>Diabetes mellitus</li> <li>Metabolic syndrome</li> <li>Hypogonadism</li> <li>Hyperthyroidism</li> <li>Hyper- and hypocortisolism (Cushing's disease, etc.)</li> <li>Panhypopituitarism and multiple endocrine disorders</li> </ul>
Respiratory disease	<ul><li>Chronic obstructive pulmonary disease</li><li>Sleep apnoea</li></ul>
Nutritional disturbances	<ul> <li>Malnutrition</li> <li>Zinc deficiency</li> </ul>
Hematologic-related	Sickle cell anaemia     Leukaemia
Psychogenic-related	<ul> <li>Disorders of sexual intimacy</li> <li>Depression</li> <li>Stress</li> <li>Performance anxiety</li> <li>Post-traumatic stress disorder</li> <li>Psychosis</li> </ul>
Non-pathological causes	
Surgical procedures	<ul> <li>Brain and spinal cord procedures</li> <li>Retroperitoneal or pelvic lymph node dissection</li> <li>Aortoiliac or aortofemoral bypass</li> <li>Abdominal perineal resection</li> <li>Proctocolectomy</li> <li>Transurethral resection of the prostate</li> <li>Radical prostatectomy</li> <li>Cryosurgery of the prostate</li> <li>Cystectomy</li> </ul>
Medications that can cause or exacerbate symptoms	<ul> <li>Antihypertensives (beta-blockers, verapamil, methyldopa, and clonidine)</li> <li>Diuretics (spironolactone and thiazides)</li> <li>Antidepressants (tricyclics, monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), lithium, and venlafaxine)</li> <li>Antipsychotics (chlorpromazine, haloperidol, and phenothiazines)</li> <li>Antiarrhythmic agents (digoxin and amiodarone)</li> <li>Anticholinergics (pregabalin, gabapentin, and duloxetine)</li> <li>Antiepileptics (carbamazepine, topiramate, gabapentin, and pregabalin)</li> <li>Hormones and hormone-modifying medicines:anti-androgens (such as cyproteroneacetate); gonadotrophin-releasing hormone agonists (such as leuprorelin, goserelin); oestrogens; progesterone.</li> <li>5-alpha reductase inhibitors (e.g., finasteride and dutasteride)</li> <li>Antiulcer agents (e.g., cimetidine and ranitidine)</li> <li>Cytotoxic agents (cyclophosphamide and methotrexate)</li> </ul>

Causes	Examples
Recreational drugs	<ul> <li>Heroin, cocaine, cannabis, methadone, synthetic drugs, anabolic steroids, excessive alcohol intake.</li> </ul>

## 2.5 Signs and symptoms

While occasional difficulties with erections are common and not necessarily a cause for concern, persistent or recurrent symptoms may indicate ED and warrant further assessment. The onset of ED can be gradual, with a worsening of symptoms over time, or it can be sudden. ED manifests itself through a variety of symptoms that can affect a man's sexual performance and overall quality of life. The main symptoms include:<sup>26, 27</sup>

- **Difficulty achieving an erection:** Men with ED may have difficulty achieving an erection despite sexual stimulation.
- **Difficulty maintaining an erection:** Even when an erection is achieved, men with ED may find it difficult to maintain it throughout sexual activity.
- Reduced firmness of erections: The quality of erections may be affected, with less firmness than usual.
- Premature or delayed ejaculation: Problems with ejaculation can sometimes accompany ED.
- **Reduced sexual desire or libido:** Although not always present, some men with ED may experience a decrease in their interest in sexual activity.
- Complete inability to get an erection: In severe cases, men may not be able to get an erection at any time.

Identifying the symptoms of ED early is crucial for timely intervention and appropriate management. ED may indicate underlying health problems, such as cardiovascular disease, diabetes, or hormonal imbalances, highlighting the need for a thorough assessment by healthcare professionals. However, many men delay seeking medical help despite experiencing symptoms. This delay may be influenced by factors such as embarrassment, lack of awareness about treatment options, or misconceptions about the condition. Notably, despite the availability of public awareness campaigns and online resources, there remains a significant need to raise awareness among men about the importance of ED as a sentinel marker of overall health and the need to seek professional healthcare support.<sup>28</sup>

This delay highlights the critical role of pharmacists in recognising ED symptoms early and encouraging patients to seek timely intervention. Pharmacists play a key role in identifying potential signs of ED, providing guidance, and encouraging patients to pursue appropriate care. By facilitating open and non-judgmental discussions, they can help patients address their concerns and access appropriate treatment options. For example, given the strong association between hypertension and ED, blood pressure monitoring in the pharmacy setting can be a valuable tool for early detection and risk assessment, as well as a starting point for discussion on the topic.

## 2.6 Common risk factors

As mentioned in the Aetiology section, ED is influenced by a variety of physiological, psychological, iatrogenic, and lifestyle factors. Although the aetiology of ED is complex, several common risk factors have been extensively studied for their contribution to the development and progression of ED.<sup>16, 20, 21</sup> These include, among others, advancing age, comorbidities such as cardiovascular disease, diabetes, obesity, as well as certain pharmacological treatments.<sup>16</sup> Although these factors do not directly cause ED, they can increase susceptibility or exacerbate its severity. Understanding these risk factors enables pharmacists to assess and manage ED more effectively. Addressing modifiable factors through lifestyle interventions and appropriate medical treatment can help reduce both the incidence and severity of ED. Figure 3 provides an overview of the most common risk factors associated with erectile dysfunction, as explored in this section.

Figure 3 – Common risk factors for erectile dysfunction



## 2.6.1 Coexisting medical conditions

Whilst we know that ED is not an inevitable consequence of ageing, advancing age is a significant contributing factor. The prevalence of ED increases with age due to age-related physiological changes such as reduced testosterone levels, vascular impairment, and the presence of comorbidities, all of which can negatively impact erectile function.<sup>17</sup>

Common medical conditions associated with ED include:

- Cardiovascular disease: Conditions such as hypertension, coronary artery disease, and atherosclerosis are
  closely linked to ED. These vascular disorders reduce blood flow to the penis, affecting erectile function. Many
  men experience ED as an early indicator of cardiovascular disease.<sup>17</sup>
- **Diabetes mellitus**: Both type 1 and type 2 diabetes are strongly associated with ED due to their effects on vascular and nerve function. Diabetes-related neuropathy and endothelial dysfunction impair erectile response. <sup>17</sup> Effective blood glucose control can reduce the risk and severity of ED.
- Metabolic syndrome (MetS): MetS, a cluster of conditions including insulin resistance, hypertension, dyslipidaemia, and central obesity, is a recognised risk factor for ED. These metabolic disturbances contribute to endothelial dysfunction and impaired circulation, which negatively affect erectile function.<sup>16, 17</sup>
- Urological conditions: Erectile dysfunction is frequently associated with various urological conditions, highlighting the connection between urological health and erectile function. Men with lower urinary tract symptoms (LUTS), often linked to benign prostatic hyperplasia (BPH), have an increased risk of ED, as both conditions may share common pathophysiological mechanisms. Additionally, chronic pelvic pain syndrome, chronic prostatitis, bladder pain syndrome (interstitial cystitis), and premature ejaculation have also been linked to ED. Furthermore, surgical procedures such as urethroplasty for posterior urethral strictures and interventions for LUTS/BPH can contribute to erectile dysfunction.<sup>16</sup>
- **Hypogonadism**: Low testosterone levels are associated with reduced libido and impaired erectile function. <sup>17</sup> Hypogonadism may be primary or secondary and can coexist with metabolic syndrome and diabetes.

## 2.6.2 Lifestyle choices

Unhealthy lifestyle habits contribute significantly to both the development and severity of ED. Key modifiable risk factors include: 13

- **Tobacco use:** Tobacco use accelerates endothelial dysfunction and atherosclerosis, leading to reduced penile blood flow and an increased risk of ED.
- Excessive alcohol consumption: Excessive and chronic alcohol use is associated with both vascular and neurological impairments that adversely affect erectile function.
- **Physical inactivity:** A sedentary lifestyle is associated with obesity, metabolic disorders, and poor cardiovascular health, all of which are established risk factors for ED.
- **Poor diet:** Diets high in processed foods, saturated fat and added sugars can contribute to cardiovascular and metabolic conditions that are associated with ED.

Given the strong link between lifestyle and ED, pharmacists have an important role to play in promoting healthier lifestyle choices. Through patient education, tobacco cessation interventions, alcohol reduction counselling, and advice on diet and physical activity, pharmacists can help individuals adopt preventive strategies that improve overall health and reduce the risk of ED.

## 2.6.3 Psychological factors

- **Stress and anxiety**: Psychological stress can interfere with the neurochemical signalling required for an erection. A cycle can develop in which ED increases anxiety, making the condition worse.<sup>17</sup>
- Depression: Depression significantly affects libido and sexual performance. In addition, some antidepressants, particularly selective serotonin reuptake inhibitors (SSRIs), are associated with sexual side effects, including ED.<sup>17</sup>
- Relationship problems and self-esteem: Difficulties with emotional intimacy, unresolved conflicts and low self-esteem can negatively affect erectile function, creating a cycle of psychological distress that further exacerbates the condition.

## 2.6.4 Medications contributing to erectile dysfunction

Erectile dysfunction can be a side effect of many medications, especially those prescribed for common health conditions.

- Antihypertensive medications: Some blood pressure medications, such as diuretics and beta-blockers, have been linked to ED. These medicines may reduce blood flow to the penis or interfere with the hormonal regulation of erectile function.
- Antidepressants: SSRIs and other antidepressants are commonly associated with sexual dysfunction, including ED, as they alter neurotransmitter activity involved in sexual arousal and erection.
- **Antipsychotics and antihistamines**: Certain antipsychotic medications and antihistamines can interfere with neurotransmitter pathways involved in erectile function, leading to potential sexual side effects.
- Hormonal treatments for prostate cancer: Androgen deprivation therapy and other hormonal treatments
  used in prostate cancer management can significantly impact erectile function by suppressing testosterone
  production.
- **Recreational substances**: Excessive alcohol consumption, amphetamines, and other drugs used for recreational purposes may contribute to ED by affecting vascular, neurological, and hormonal systems.

It is important to note that while these medications may contribute to ED, patients should not discontinue any prescribed treatments without consulting their prescriber. Pharmacists and other healthcare professionals play a crucial role in identifying medication-related ED and exploring alternative treatments or dosage adjustments to manage both the primary condition and erectile dysfunction symptoms effectively. Further examples of medications that may cause or exacerbate ED symptoms are listed in Table 2.

# 3 Assessment and diagnosis

Identifying and assessing risk factors for ED is a crucial part of the diagnostic process. Pharmacists, as accessible healthcare professionals, can play a key role in identifying potential underlying conditions, providing guidance on self-care strategies and referring patients when appropriate. This chapter explores key aspects of ED assessment, including visual cues to identify health risks, recommended assessment tools, and key red flags that indicate the need for specialist referral.

## 3.1 Observing visual cues to identify health risks

As described in section 2.6 on Common risk factors, pharmacists are in a unique position to identify potential health risks associated with ED through patient interactions and observations. While a formal diagnosis of ED may require physician input, pharmacists can recognise signs suggestive of underlying medical conditions that contribute to ED, such as:17,24

- Obesity and metabolic syndrome: Central obesity, particularly increased waist circumference, is a strong
  indicator of metabolic disturbances that may contribute to ED. Identifying when a patient appears overweight
  can lead to suggestions for lifestyle changes, such as dietary changes and increased physical activity, as well as
  further assessment. By offering weight management advice and referring patients to appropriate services,
  pharmacists can support long-term improvements in cardiovascular and metabolic health.
- Cardiovascular health indicators: Visible signs such as cyanosis or oedema may indicate vascular problems, including atherosclerosis or hypertension, which are closely associated with ED. Pharmacists can advise patients to monitor blood pressure and cholesterol levels and encourage cardiovascular health screening. They can also provide advice on how to lead a heart-healthy lifestyle, including a healthy diet, adequate exercise and medication adherence.
- **Tobacco-related signs**: Yellow fingers and teeth, persistent cough or breathlessness may indicate chronic tobacco use, a known risk factor for ED due to endothelial dysfunction. Pharmacists can initiate discussions about tobacco cessation and recommend appropriate nicotine replacement therapies and behavioural support programmes. By actively engaging in tobacco cessation counselling, pharmacists can help reduce ED risk and improve overall vascular health.
- **Signs of depression or anxiety**: Poor eye contact, flat affect or psychomotor retardation may indicate underlying mental health issues that are often associated with ED. By recognising these cues, pharmacists can provide information about mental health support services and encourage patients to seek professional mental health care. Additionally, they can offer tailored strategies to help men manage stress and anxiety, which can improve mental well-being and contribute to better sexual health.

By recognising these cues and incorporating physical and mental health observations into routine patient interactions, pharmacists can initiate discussions about ED risk factors, encourage further assessment and provide comprehensive care.

## 3.2 Recommended screening and assessment tools

Several validated tools and screening methods can assist pharmacists in assessing the severity of ED and identifying underlying causes. While pharmacists do not perform diagnostic tests, they can recommend or facilitate access to the following assessment tools to enable early identification of patients who may benefit from further evaluation and treatment.

## 3.2.1 Assessing psychosexual factors

- Sexual health history: Assess the onset, duration, and progression of ED. Key aspects include libido, arousal, ejaculation, orgasm, and quality of erections (morning, spontaneous, self-stimulated, and partner-related). A gradual onset with diminished spontaneous erections may suggest an organic cause, whereas a sudden onset of symptoms, low libido, and good quality spontaneous or self-stimulated erections may suggest a psychogenic origin.<sup>19</sup>
- Psychosocial factors: Psychological and interpersonal factors may play an important role in ED. Pharmacists should assess stress, anxiety, depression and relationship difficulties as these may contribute to sexual dysfunction. In addition, issues related to sexual aversion or pain, cultural or religious beliefs, and sexual partner concerns (including sexual desire, satisfaction or discomfort) should be explored. Other contributing factors, such as recent childbirth, intimacy difficulties, previous sexual trauma or abuse, and underlying psychological conditions, should also be considered. Pharmacists can support patients by discussing mental well-being and signposting to counselling or psychological support services as appropriate.<sup>19</sup>
- **Validated questionnaires**: Pharmacists can use or recommend the following tools to assess ED severity and its impact on quality of life:
  - o <u>International Index of Erectile Function (IIEF)</u>: The IIEF is a validated, multidimensional, self-administered questionnaire used to assess ED and treatment outcomes in clinical trials. It consists of 15 questions that assess five key domains of male sexual function: erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. Each question is scored on a scale of 0 to 5, with the total score helping to determine the severity of ED. This tool is widely used in both clinical practice and research to aid diagnosis and monitor the effectiveness of treatment. It includes questions that assess different aspects of sexual activity such as sexual stimulation, ejaculation and orgasm, providing a comprehensive assessment of a patient's sexual health.<sup>29</sup>
  - Sexual Health Inventory for Men (SHIM): The SHIM questionnaire, also known as the IIEF-5, is a condensed and slightly modified five-item version of the original 15-item International Index of Erectile Function. It was designed to provide a quick and reliable assessment of ED severity in clinical settings. This tool can help reduce cases of misdiagnosis or underdiagnosis and is intended to complement the patient's medical history and physical examination in identifying ED and determining its severity. Given the strong link between ED and other medical conditions, early and accurate assessment is essential for guiding appropriate treatment and identifying potential underlying health concerns.<sup>30</sup>

## 3.2.2 Reviewing medical history

A well-structured medical history is essential to identify potential factors contributing to ED. Pharmacists should consider the presence of comorbidities such as hypertension, diabetes and metabolic syndrome, as well as LUTS associated with ED. Previous pelvic surgery, including radical prostatectomy or bladder surgery, may also affect erectile function. In addition, as mentioned in section 2.6.4, a review of medication use is necessary. Lifestyle factors, including tobacco use, excessive alcohol consumption, poor diet and sedentary lifestyle, should also be assessed as they are important modifiable contributors to the risk of ED. Through this assessment, pharmacists can identify potential causes, provide lifestyle advice and determine the need for further medical assessment or referral.<sup>19</sup> Further guidance on how to start conversations and conduct an initial consultation in the pharmacy is provided in Chapter 6. This includes examples of questions that can help explore an individual's medical history and support them in a people-centred approach.

#### 3.2.3 Screening tests

Certain screening tests can help assess underlying medical conditions associated with ED. Pharmacists in many community pharmacies around the world can perform point-of-care tests for cardiovascular and metabolic risk factors, while more specialised hormonal and disease-specific tests require medical referral. Key tests include: 19, 31

• **Glucose control tests**: HbA1c or fasting glucose testing may be recommended in patients with suspected diabetes or metabolic syndrome.

 Cardiovascular risk assessment: Blood pressure measurement and lipid profile screening can help identify cardiovascular risk factors contributing to ED. The 10-year cardiovascular risk can be calculated to guide prevention and management strategies.

For further evaluation, physicians may request additional tests, including: 16, 19, 24

- **Hormonal assessment:** Fasting serum testosterone levels (taken between 9–11am) to assess for hypogonadism, with follow-up tests such as follicle-stimulating hormone (FSH), luteinising hormone (LH), sex hormone-binding globulin (SHBG), and prolactin if levels are low or borderline.
- Prostate-specific antigen (PSA): To assess prostate health, particularly in men at risk of prostate cancer.
- Thyroid function tests: To identify hyperthyroidism or hypothyroidism, which can contribute to ED.
- Liver and renal function tests: To assess for underlying conditions affecting metabolism and circulation.

In addition, certain functional tests may be used in specialist settings where further assessment is required. These include:  $^{16, 24, 31}$ 

- Intracavernosal injection test: The direct injection of prostaglandin E1 (alprostadil) into the corpora cavernosa to assess penile vascular function. A combination of alprostadil with papaverine and phentolamine may also be used
- Nocturnal penile tumescence and rigidity test: Evaluates the presence of spontaneous erections during sleep, helping to differentiate between organic and psychogenic causes of ED. This test involves the use of nocturnal monitoring devices to measure the number, duration, and rigidity of nocturnal erections over at least two nights. An erectile event with at least 60% rigidity lasting ten minutes at the penile tip is considered a functional response.
- Biothesiometry: A test that measures penile vibratory sensitivity to assess potential nerve dysfunction.
- **Dynamic duplex ultrasound of the penis**: A second-level diagnostic test that evaluates penile blood flow and vascular abnormalities, particularly in men with suspected vasculogenic ED.
- **Arteriography and cavernosography**: Rarely used, but may be indicated by physicians in patients being considered for penile revascularisation or in those with suspected venogenic ED.

By offering screening services where possible and referring patients to a physician when further medical evaluation is needed, pharmacists can contribute to the early detection and management of ED-related conditions. Guidance on when referral is appropriate can be found in the section 3.3, Identifying red flags and when to refer.

#### 3.2.4 Physical examination

A physical examination should be conducted by a physician to assess potential underlying causes of ED. This includes evaluating secondary sexual characteristics, such as gynaecomastia, sparse body hair, or reduced muscle mass, which may indicate testosterone deficiency. Examination of the external genitalia can help identify conditions such as Peyronie's disease, hypospadias, phimosis, or signs of penile cancer. <sup>16, 17</sup> Testicular abnormalities, including atrophy, lumps, or swelling, may indicate underlying endocrine or urological conditions. In some cases, a digital rectal examination is necessary to assess prostate abnormalities, particularly in men with LUTS or a history of prostate cancer. <sup>19</sup>

## 3.3 Identifying red flags and when to refer

Pharmacists play a crucial role in identifying red flags and ensuring timely referral for patients with diagnosed or suspected ED. Erectile dysfunction is a red-flag symptom in itself, as it can indicate underlying cardiovascular disease or other serious conditions. The following situations indicate when referral to a physician or specialist is necessary:

 Cardiovascular disease: ED is often an early indicator of cardiovascular disease. Newly presenting patients should undergo a thorough cardiovascular and endocrine risk assessment, with appropriate management strategies implemented. Patients should be informed that ED is a significant indicator of underlying heart disease and referred for further cardiovascular risk assessment and treatment. Cases of severe cardiovascular disease that make sexual activity unsafe or contraindicate the use of PDE-5 inhibitors should be referred to cardiology.<sup>17, 31, 32</sup>

- Penile abnormalities: When patients disclose or present with conditions such as Peyronie's disease, penile
  curvature, palpable plaques or testicular irregularities, pharmacists should provide appropriate referral to a
  urologist for further assessment and care.<sup>32</sup>
- **Treatment resistance**: Patients who do not respond to the maximum dose of at least two phosphodiesterase-5 inhibitors (PDE5Is) should be referred for specialist evaluation.<sup>32</sup>
- Hormonal issues: Suspected hypogonadism or testosterone deficiency should prompt endocrinological assessment.<sup>32</sup>
- **Neurological conditions**: Patients with neurological disorders affecting erectile function may require specialist care.
- Psychological distress: Severe emotional distress or evidence of primary psychogenic ED should be addressed through psychosexual counselling.<sup>32</sup>
- Other red flags: Persistent ED in young men, priapism (erections lasting more than four hours), severe renal or kidney impairment, pelvic surgery or radical non-nerve sparing prostatectomy or contraindications to PDE5I use (e.g., concurrent nitrate therapy) require further assessment.<sup>32</sup>

By recognising these red flags and making appropriate referrals, pharmacists can ensure that patients receive comprehensive care and that potentially serious underlying conditions are not overlooked.

# 4 Pharmacological management

Pharmacological treatments for erectile dysfunction (ED) have advanced significantly in recent years, providing a range of options that can be tailored to individual patient needs and preferences. These treatments can be broadly classified into oral medications, intracavernosal injections, and intraurethral agents. Each category offers distinct benefits and is supported by extensive clinical evidence, enabling healthcare providers to offer personalised treatment plans. While oral phosphodiesterase-5 inhibitors (PDE5Is) remain the first-line pharmacological treatment for many, injectable and intraurethral therapies offer effective alternatives for patients who do not respond, or do not respond adequately, to oral treatments, further expanding the available options for managing ED.<sup>33</sup>

In the management of ED, the primary objective is to enable the individual or couple to enjoy a satisfactory sexual experience. Beyond efficacy and safety, it is important to consider patient and partner preferences, as well as any factors that may influence treatment choices. It is equally crucial to address any undiagnosed comorbidities discovered during the patient assessment, treating existing conditions and making necessary lifestyle modifications.<sup>34</sup> Except for cases of psychogenic, hormonal and post-traumatic arteriogenic ED in young men, which are potentially solvable causes, pharmacotherapy allows for successful treatment of the disease, but not a complete cure. Medication can be used in two of the three stages of ED treatment: oral treatments, and intracavernosal or intraurethral therapy, while penile prosthesis is reserved for third-line intervention.<sup>35</sup>

The latest European Urology Guidelines set out a structured decision-making process for the available alternatives, highlighting the benefits of personalised treatment for each patient based on tolerance, effectiveness and the invasiveness of the technique. It also identified adverse effects, cost, ineffectiveness and/or the quality of sexual relations as the main barriers to the real use of treatments.<sup>16</sup>

**First-line treatment interventions** include lifestyle and risk factor modification alongside the use of PDE5Is or a vacuum erection device. **Second-line treatment options** consist of intracavernosal injection therapy, intraurethral alprostadil, alprostadil cream, or low-intensity extracorporeal shock wave therapy. **Third-line treatment** involves the use of a penile prosthesis.<sup>34</sup>

## 4.1 Phosphodiesterase type 5 inhibitors

#### 4.1.1 Introduction to PDE5Is

The first-line treatment for ED typically involves oral phosphodiesterase type 5 inhibitors (PDE5Is), with the advantages of high safety, good effect and non-invasiveness.<sup>36</sup> For a better understanding of its mechanism of action, it should be remembered that the enzyme phosphodiesterase type 5 (PDE5) hydrolyses cyclic guanosine monophosphate (cGMP) in the corpus cavernosum tissue of the penis. The inhibition of this enzyme results in an increase in the production of nitric oxide, which mediates smooth muscle relaxation and enhances vasodilation and arterial blood flow, favouring penile erection. It is important to make it clear to the patient that this medication does not initiate an erection, but rather requires sexual stimulation to achieve sufficient rigidity of the penis to enable satisfactory sexual intercourse, thereby proving the effectiveness of the treatment.<sup>35</sup>

To date, four selective PDE5Is have been approved by the European Medicines Agency for the treatment of erectile dysfunction: **sildenafil**, **tadalafil**, **vardenafil** and **avanafil**. A summary of their main characteristics is provided in Table 3. Recommended daily doses are shown, although adjustments may be necessary in patients with renal or hepatic impairment, and concomitant use of CYP3A4 inhibitors. As a concomitant use of CYP3A4 inhibitors.

Ideally, the choice between medications should be guided by the patient's preferences, taking into account factors such as frequency of sexual activity, cost, desired duration of action, ease of use, potential side effects, and previous experience with medications.

Table 3 – Phosphodiesterase type 5 inhibitors<sup>16</sup>

Sildenafil		
Initial dosing	50 mg	
Max dosing	100 mg	
Onset of action	30-60 min	
Duration of action	4-6 h	
Side effects • Headache		
	<ul> <li>Hot flushes</li> <li>Dyspepsia</li> <li>Nasal congestion</li> <li>Abnormal vision</li> <li>Dizziness</li> </ul>	
<ul> <li>Contraindications</li> <li>Concomitant use of organic nitrates or riociguat/ vericiguat</li> <li>Patients who are advised against sexual activity due to serious heart disease, s pectoris or congestive heart failure</li> <li>Patients with a history of recent (&lt;6 months) myocardial infarction or stroke</li> <li>Acute liver or kidney failure</li> <li>Low or high blood pressure</li> <li>Inherited degenerative retinal disease (e.g., retinitis pigmentosa) or loss of visi due to non-arteritic anterior ischemic optic neuropathy (NAION)</li> </ul>		
Pharmacy interventions/ special considerations	<ul> <li>High-fat diets can delay absorption</li> <li>Take with water and on an empty stomach—onset of activity may be delayed with food</li> <li>Treatment may need to be taken a number of times on different occasions before patient can achieve a penile erection satisfactory for sexual pleasure</li> </ul>	
Examples of available formulations	<ul> <li>Tablet</li> <li>Orodispersible tablet</li> <li>Chewable tablet</li> <li>Oral spray solution</li> </ul>	
Tadalafil		
Initial dosing	10 mg	
Max dosing	20 mg	
Onset of action	30 min	
Duration of action	36 h	
Side effects	<ul> <li>Headache</li> <li>Dyspepsia</li> <li>Nasal congestion</li> <li>Hot flushes</li> <li>Back pain</li> <li>Muscle pain</li> </ul>	
Contraindications	<ul> <li>Concomitant use of organic nitrates or riociguat/ vericiguat</li> <li>Patients who are advised against sexual activity due to serious heart disease, such as angina pectoris or congestive heart failure</li> <li>Patients with a history of recent (&lt;6 months) myocardial infarction or stroke</li> <li>Acute liver or kidney failure</li> <li>Low or high blood pressure</li> <li>Inherited degenerative retinal disease (e.g., retinitis pigmentosa) or loss of vision in one eye due to non-arteritic anterior ischemic optic neuropathy (NAION)</li> </ul>	
Pharmacy interventions/ special considerations	<ul> <li>It does not interact with high-fat diets</li> <li>Take with or without food</li> <li>It has been approved for treating the symptoms of prostatic hyperplasia: it acts on both diseases</li> </ul>	

	Treatment may need to be taken a number of times on different occasions before patient
Examples of available	can achieve a penile erection satisfactory for sexual pleasure  Tablet
formulations	
Vardenafil	
Initial dosing	10 mg
Max dosing	20 mg
Onset of action	30 min
Duration of action	4 h
Side effects	<ul> <li>Headache</li> <li>Hot flushes</li> <li>Nasal congestion</li> <li>Dyspepsia</li> <li>Dizziness</li> <li>Vision abnormalities</li> </ul>
Contraindications	<ul> <li>Concomitant use of organic nitrates or riociguat/ vericiguat</li> <li>Patients who are advised against sexual activity due to serious heart disease, such as angina pectoris or congestive heart failure</li> <li>Patients with a history of recent (&lt;6 months) myocardial infarction or stroke</li> <li>Acute liver or kidney failure</li> <li>Low or high blood pressure</li> <li>Inherited degenerative retinal disease (e.g., retinitis pigmentosa) or loss of vision in one eye due to non-arteritic anterior ischemic optic neuropathy (NAION)</li> </ul>
Pharmacy interventions/ special considerations	<ul> <li>High-fat diets may delay absorption</li> <li>Treatment may need to be taken a number of times on different occasions before patient can achieve a penile erection satisfactory for sexual pleasure</li> </ul>
Examples of available formulations	<ul> <li>Tablet</li> <li>Orodispersible tablet</li> <li>Nasal spray</li> </ul>
Avanafil	
Initial dosing	100 mg
Max dosing	200 mg
Onset of action	15-30 min
Duration of action	6 h
Side effects	<ul> <li>Headache</li> <li>Hot flushes</li> <li>Nasal congestion</li> <li>Dizziness</li> <li>Back pain</li> <li>Myalgia</li> </ul>
Contraindications	<ul> <li>Concomitant use of organic nitrates or riociguat/ vericiguat</li> <li>Patients who are advised against sexual activity due to serious heart disease, such as angina pectoris or congestive heart failure</li> <li>Patients with a history of recent (&lt;6 months) myocardial infarction or stroke</li> <li>Acute liver or kidney failure</li> <li>Low or high blood pressure</li> <li>Inherited degenerative retinal disease (e.g., retinitis pigmentosa) or loss of vision in one eye due to non-arteritic anterior ischemic optic neuropathy (NAION)</li> </ul>
Pharmacy interventions/ special considerations	It does not interact with food

	Treatment may need to be taken a number of times on different occasions before patient can achieve a penile erection satisfactory for sexual pleasure
Examples of available	Tablet
formulations	

## Pharmacist considerations when suppling PDE5 inhibitors

When advising patients on PDE5Is, pharmacists should consider the following points based on the summary of product characteristics of the various available formulations:

- Clinical equivalence: While sildenafil was the first PDE5I introduced to the market and remains the most
  extensively studied in terms of safety, current scientific evidence suggests that all four PDE5Is are clinically
  equivalent. When taken at equivalent doses, they enable patients to achieve erections following appropriate
  sexual stimulation, with similar success rates.
- Dosing and timing: As a general recommendation, patients should not take more than one tablet per day.
  Sildenafil, tadalafil and vardenafil are typically taken on an as-needed basis, approximately 60 minutes before
  sexual activity (although a faster response may occur). Avanafil and orodispersible formulations of vardenafil
  can be taken 30 minutes prior to intercourse. Intranasal vardenafil, where available, has an even faster onset
  of action.
- **No STI protection:** None of these medications offer any protection against sexually transmitted infections (STIs).
- Adverse effects requiring medical attention: Patients should seek immediate medical assistance if they experience an erection lasting more than four hours (priapism) or any changes in vision.
- **Impact on driving:** Patients should be advised to avoid driving or operating heavy machinery if they experience dizziness, visual disturbances, or other side effects that may impair their ability to drive safely.
- Daily tadalafil: Tadalafil is safe, well tolerated and effective for daily use, which makes it ideal for sexually
  active couples who prefer frequent, spontaneous intercourse without planning around medication timing. This
  treatment should be re-evaluated by a specialist at regular intervals.
- **Use in penile rehabilitation:** PDE5Is, but more commonly daily tadalafil, are also used for penile rehabilitation following prostatectomy.<sup>37</sup>

## 4.1.2 Safety concerns for PDE5Is

PDE5Is are generally well tolerated, but their use is associated with specific safety considerations. Below are the key aspects pharmacists should be aware of when dispensing or supplying these medications.



## **Common side effects**

Most common side effects are headache, dizziness, visual disturbances (colour distortion, disturbance or blurred vision), flushing and warmth, nasal congestion, nausea, dyspepsia, back and limb pain, and myalgia. <sup>16</sup>



#### Visual disturbances at high doses

High doses of sildenafil (and also vardenafil) may cause visual disturbances, such as transient disturbances in colour vision (blue vision, cyanopsia), increased sensitivity to light, or blurred vision, as a result of the inhibition of retinal phosphodiesterase 6, which can lead to a change in colour sensitivity and perception. This effect can appear 1-3 hours after taking the dose, peaking at 3-4 hours.<sup>35</sup>



#### **Cardiovascular safety**

Caution should be exercised when prescribing and dispensing this type of medication to patients with existing cardiovascular disease or those at risk of developing it.<sup>16</sup>



#### Warning signs requiring immediate medical attention

The following signs and symptoms should be clearly communicated to patients as potential warning signs that may require immediate interruption of treatment and urgent consultation with a physician, in accordance with the information specified in the summary of product characteristics of the medicines that contain a PDE5I:

- Postural or orthostatic hypotension, i.e., dizziness or light-headedness (leading to fainting in the most serious cases) when standing up after sitting or lying down.
- Sudden loss or alteration of vision or hearing. Requires evaluation by an ophthalmologist, as it is usually a reversible process, but adequate study is necessary.
- Priapism: prolonged and sometimes painful erection lasting more than four hours.



#### Contraindications for the concomitant use of organic nitrates and nicorandil

The concomitant use of PDE5Is with any form of organic nitrate (including nitroglycerin) or nitric oxide (NO) donors, such as nicorandil and r substances used for recreational purposes like amyl nitrite or nitrate ("poppers"), is an absolute contraindication. This combination leads to excessive accumulation of cyclic guanosine monophosphate (cGMP), resulting in unpredictable and potentially severe drops in blood pressure, with a high risk of symptomatic hypotension. Nicorandil, due to its NO-donating properties, further increases cGMP levels, exacerbating this risk.<sup>16</sup>



## Other contraindications and cautions

Table 4 provides a summary of contraindications and precautions for prescribing PDE5Is.

Table 4 – Contraindications and precautions for PDE5Is<sup>19</sup>

Contraindications for PDE5Is	Precautions for PDE5Is	Precaution: Co-administration of sildenafil with sacubitril/valsartan
<ul> <li>Unstable angina or angina occurring during sexual intercourse</li> <li>Regular or intermittent use of nitrates in any form—risk of severe, life-threatening hypotension</li> <li>Hypotension (systolic blood pressure below 90 mmHg)</li> <li>History of non-arteritic anterior ischaemic optic neuropathy (NAION)</li> <li>Recent history of myocardial infarction (within 90 days for tadalafil)</li> <li>Recent history of stroke</li> <li>Heart failure (mild to severe; tadalafil, and avanafil)</li> <li>Uncontrolled arrhythmias (tadalafil and avanafil)</li> <li>Uncontrolled hypertension (tadalafil and avanafil)</li> <li>Severe hepatic impairment (sildenafil, vardenafil film-coated tablets, and avanafil); moderate-to-severe (vardenafil orodispersible tablets)</li> </ul>	<ul> <li>Cardiovascular disease</li> <li>Left ventricular outflow obstruction (for example, aortic stenosis and idiopathic hypertrophic subaortic stenosis)</li> <li>Anatomical deformity of the penis (for example, angulation, cavernosal fibrosis, or Peyronie's disease)</li> <li>A predisposition to priapism (for example, sickle-cell disease, multiple myeloma, or leukaemia)</li> <li>Active peptic ulceration or bleeding disorders (sildenafil, vardenafil, and avanafil)</li> <li>Hepatic impairment (sildenafil—consider initial dose reduction if mild-to-moderate impairment); severe hepatic impairment (tadalafil); mild-to-moderate (caution if vardenafil film-coated tablets or avanafil); mild (caution if</li> </ul>	A single dose of sildenafil significantly reduces blood pressure in individuals with hypertension

Contraindications for PDE5Is	Precautions for PDE5Is	Precaution: Co-administration of sildenafil with sacubitril/valsartan
<ul> <li>Renal impairment (creatinine clearance less than 30 mL/min; avanafil)</li> <li>A hereditary degenerative retinal disorder, such as retinitis pigmentosa (sildenafil, vardenafil, and avanafil)</li> </ul>	vardenafil orodispersible tablets)  Renal impairment (creatinine clearance less than 30 mL/min, sildenafil and vardenafil— consider initial dose reduction); severe renal impairment (tadalafil—avoid regular once- daily dosing and consider dose reduction for intermittent use)  Susceptibility to prolongation of QT interval, or older age (vardenafil)  Autonomic dysfunction	

#### Pharmacological interactions (see Table 5 for details).

The concomitant use of certain medications may necessitate an adjustment in the PDE5I dose.

- Alpha-blockers may cause symptomatic hypotension (dizziness, light-headedness) when used concomitantly
  with PDE5Is, so caution is advised when they are combined, especially among subgroups of patients more
  susceptible to hypotension and within four hours of taking the PDE5I. Patients should be haemodynamically
  stable before starting ED treatment, considering the use of a PDE5I at the lowest effective dose. Should this be
  the only therapeutic option, the best choices would be tamsulosin and silodosin, which would cause less
  hypotension (vs. doxazosin or terazosin).
- When used with other **antihypertensive medication**: a decrease in blood pressure figures should be taken into account due to potential additive hypotensive effects with other types of medication such as calcium channel blockers (e.g., amlodipine), angiotensin converting enzyme inhibitors (e.g., enalapril), beta-blockers (e.g., metoprolol) and/or angiotensin II receptor blockers (e.g., valsartan), among others. Clinical study results are inconclusive regarding the clinical significance of the interaction.
- **CYP3A4 inhibitors**: For patients using medication that inhibits the CYP3A4 metabolic pathway (e.g., ketoconazole, ritonavir, itraconazole, clarithromycin, erythromycin, etc.), these should be avoided as they increase the blood levels of PDE5Is. Should they be used at the same time, the dose of the latter should be reduced.
- **CYP3A4 inducers**: On the other hand, CYP3A4-inducers (e.g., carbamazepine, phenytoin, rifampicin, etc.) would decrease the available dose of PDE5Is, requiring higher doses of these.
- Alcohol: Consumption of large amounts of alcohol poses not only a risk factor for the development of erectile
  dysfunction but also an element of interaction to the pharmacological treatment of this condition. Alcohol
  consumption produces a hypotensive effect in addition to that produced by PDE5Is and is also associated with
  greater difficulty in achieving or maintaining a penile erection due to its central nervous system depressant
  effect.

Table 5 – Main interactions of PDE5Is with other medications or substances<sup>19</sup>

Medication or other substance	Effect	Recommendation
Alpha1 blockers (e.g., alfuzosin, doxazosin, tamsulosin)	Increased hypotensive effect	Refer to a prescriber first
CYP3A4 inhibitors (e.g., saquinavir, ketoconazole, itraconazole, erythromycin, cimetidine)	Increases levels of sildenafil	Refer to a prescriber first

Medication or other substance	Effect	Recommendation
Cytochrome P450 inhibitors (e.g., ketoconazole, ritonavir, erythromycin, cimetidine)	Increases levels of tadalafil	Refer to a prescriber first
Guanylate cyclase stimulators (e.g., riociguat)	Increased hypotensive effect	Contraindicated
Nitrates	Increased hypotensive effect	Contraindicated
Nitric oxide donors (e.g., nicorandil, molsidomine, amyl nitrite 'poppers')	Increased hypotensive effect	Contraindicated
Ritonavir (highly potent P450 enzyme inhibitor)	Increases levels of sildenafil	Contraindicated
Grapefruit juice	Increases levels of sildenafil	Avoid
Ethanol	Increased hypotensive effect	Avoid

## 4.1.3 Management of non- or poor-responders to PDE5Is

No response to PDE5Is is typically due to one of two reasons: incorrect use of the medication, or lack of efficacy. In cases of incorrect use, community pharmacists can play an important role through health education and counselling (see Chapter 5).

Before concluding treatment failure, it is important that patients use the correct dosage—which may be increased, if deemed necessary by the prescriber—and try the medication on at least six separate occasions.

If there is no response despite correct use, the patient should be referred to a physician for further evaluation. It may be necessary to assess for conditions such as hypogonadism which, if present, should be treated accordingly. Sometimes, the combination of PDE5Is and testosterone therapy can improve the clinical response to these medications, particularly in patients with hypogonadism.<sup>38</sup>

For patients with severe ED, the combination of tadalafil (5 mg/day) with a shorter-acting PDE5I (e.g., sildenafil) may be considered. Although this approach has not shown a significant increase in adverse effects, it should be used with caution and only under close medical supervision, as robust evidence from randomised controlled trials is lacking.

While PDE5Is are generally considered the first-line treatment for ED — alongside appropriate management of any underlying conditions — several alternative pharmacological options are available for patients who do not respond adequately. These are discussed in sections 4.2, 4.3, 4.4, and 4.5.

#### 4.1.4 Self-medication and misuse of PDE5Is

Phosphodiesterase type 5 inhibitors are widely recognised as effective treatments for erectile dysfunction. However, their inappropriate use in the absence of medical oversight has become a growing concern. Many individuals bypass medical consultation, obtaining these medications, online or offline via illicit sources.<sup>39</sup> This practice can lead to inappropriate use, incorrect dosing, and potential medicines interactions, particularly for individuals with underlying health conditions or those taking contraindicated medications, such as nitrates.

Self-medication with PDE5Is also increases the risk of substandard or falsified products, which may contain harmful substances or incorrect dosages, exacerbating health risks. This means that it is not possible to know whether they meet the quality, safety and efficacy guarantees required for any medicine that is purchased in a pharmacy.<sup>39</sup> In addition, the recreational misuse of PDE5Is by individuals without ED, often in combination with other substances, poses additional risks, including cardiovascular complications.<sup>40</sup>

Pharmacists have an important role to play in educating patients about the correct use of PDE5Is, identifying potential misuse and stressing the importance of medical advice to ensure safety and efficacy. This role, including the ethical responsibilities of pharmacists in managing such situations, will be further explored in Chapter 7 on Pharmacists' professional and ethical responsibilities in ED management.

Broadly speaking, the most common errors regarding the use or perceived benefits of PDE5Is are as follows: a) lack of prior sexual stimulation, as PDE5Is do not induce an erection without stimulation; b) inadequate waiting time between medication intake and initiating sexual activity; or c) consumption of alcohol or food before taking the medication, either of which can reduce its effectiveness. Another common reason for lack of effectiveness is the absence of sexual desire, as these medications do not increase libido, but rather enhance the penis's response to sexual desire.

## 4.2 Intracavernosal injections therapy

Alprostadil was the first medicine approved for intracavernosal treatment of erectile dysfunction and remains one of the most widely used options in many countries. Alprostadil is a prostaglandin E1 analogue used to dilate the blood vessels of the penis by blocking alpha-1 adrenergic receptors, increasing blood flow to the corpora cavernosa and causing an erection.<sup>35</sup>

Typically, intracavernosal injections are self-administered, either by the patient or their partner, following a period of training. The dose of alprostadil varies, ranging from 5 to 40  $\mu$ g, with an erection typically occurring within 5 to 15 minutes. The duration of the erection is dependent on the dose, though it is important to note that there is significant variability between patients. A gradual adjustment of the dose is recommended, starting at 2.5  $\mu$ g until an adequate erection is achieved and lasts less than 60 minutes. A frequency of one injection per day and no more than three times per week is recommended. Self-administration of the dose is recommended.

Patient satisfaction with this treatment is generally high, but side effects such as pain in the penis are common, with some patients also experiencing prolonged erections, fibrosis, or priapism. Contraindications for the use of this type of injection include lack of tolerance to the active ingredient, conditions that predispose to priapism, anatomical deformity of the penis and patients with penile implants, men with bleeding disorders (e.g., sickle cell anaemia), or men taking anticoagulants. <sup>16, 34, 35</sup>

Alternative treatment options are available in some countries (Table 6), both in single-component and multi-component formulations. Combination therapy allows patients to benefit from the different mechanisms of action of the medicines used while also reducing adverse effects by enabling the use of lower doses of each medication. Injections of papaverine (an alkaloid derived from opium with vasodilatory effects but no action on opioid receptors), phentolamine (an alpha-1 and alpha-2 adrenergic receptors antagonist), or aviptadil (a synthetic analogue of vasoactive intestinal peptide) have been used. Among the most commonly used and with specific authorised indications in the treatment of ED is an injection formulation of 25  $\mu$ g of aviptadil and 2 mg of phentolamine, which has demonstrated similar or even slightly higher efficacy than alprostadil, with a lower incidence of penile pain and priapism. <sup>16</sup>

Table 6 – Intracavernosal injections therapy<sup>16</sup>

Medicine	Dosage	Efficacy	Side effects	Comment
Alprostadil	5-40 μg/ml	~70%	<ul><li>Penile pain</li><li>Priapism</li><li>Fibrosis</li></ul>	Indication authorised
Papaverine	20-80 mg	<55%	<ul><li>Increased liver enzymes</li><li>Priapism</li><li>Fibrosis</li></ul>	Not used as monotherapy
Phentolamine	0.5 mg/ml	Poor efficacy as monotherapy	<ul><li>Systemic hypotension</li><li>Reflex tachycardia</li><li>Nasal congestion</li><li>Gastrointestinal upset</li></ul>	Not used as monotherapy
Papaverine + phentolamine	30 mg/ml + 0.5 mg/ml	~ 90%	Similar to alprostadil monotherapy (pain less common)	Off-label use

Medicine	Dosage	Efficacy	Side effects	Comment
Papaverine + phentolamine + alprostadil	30 mg/ml + 1 mg/ml + 10 μg/ml	~ 92%	Similar to alprostadil monotherapy (pain less common)	Off-label use
Aviptadil + phentolamine	25 μg + 1-2 mg	~ 80%	Similar to alprostadil monotherapy (without pain)	Easily available

#### Correct administration technique for intracavernosal injections

Proper technique is critical to achieving the best possible outcome for patients using intracavernosal injections. A correct injection technique not only optimises the patient's experience but also reduces the risk of side effects, including priapism and plaque formation. The following key steps should be followed:

- 1. **Positioning and penile preparation**: Ideally, the patient should stand while exposing the glans and stretching the penils straight out in front of the body, holding the penile shaft directly behind the glans. This is critical to stretch and tighten the tunica albuginea to optimise the likelihood of needle penetration. The penile shaft should both appear and feel tight.
- 2. **Injection angle and needle insertion:** The needle should be injected at the correct angle into the shaft of the penis; the optimal angle is, per the clock face, 10 o'clock or 2 o'clock. This ensures that the medication is delivered into the corpus cavernosum where it will take effect while avoiding nerves, blood vessels, and the urethra. The typical needle for this injection is 12.7mm (1/2 inch) long and may be a syringe with a pre-attached needle or a syringe with a separate needle of the same length. The needle should generally be inserted to its full depth to ensure delivery of the medication to the correct structure. The injection site should be rotated to reduce the likelihood of plaque formation. While rotating between the left and right sides of the penile shaft is an option, it can be impractical. In this case, moving the injection site up or down the shaft will suffice.
- 3. **Post-injection massage and management:** After the injection, a firm massage of the full penile shaft for at least 30 seconds is essential. The cavernosal tissue runs from the base of the pubic bone to the glans of the penis, and a good, firm massage will ensure a wide distribution of the medication, resulting in a better and more reproducible effect, as well as reduced discomfort (particularly when alprostadil is used, noting the higher incidence of discomfort post-injection). In the event of bleeding, it is recommended that firm pressure be applied to the injection site for 5-60 seconds after needle removal, noting that some non-disturbing bruising may occur at the injection site which will usually resolve over the following seven days. Patients on anticoagulants are more prone to this and should be advised that this is not unusual but equally where the patient is concerned that they should seek further advice.

## Management of priapism

Globally, best practice guidelines recommend that the initial dose of intracavernosal medication be administered by or under the supervision of a healthcare professional with expertise in the technique. This allows the practitioner to provide proper instruction, assess the response to the initial dose, and offer guidance on subsequent doses. Additionally, it provides an opportunity to educate patients on priapism, which is a medical emergency.

Priapism is defined as an erection lasting more than four hours without subsiding. It is often painful and requires immediate attention to prevent damage to the penile tissue due to hypoxia. Recommended actions to manage priapism include:

- Taking a 60-120 mg dose of pseudoephedrine
- Applying an ice pack or pressure to the penis or perineum
- Taking a cool shower
- Taking a brisk walk.

If these actions fail to resolve the condition, the patient should seek immediate medical attention at a hospital or emergency department, where the erection will be relieved and pain management can be provided.

The premise of these actions is to cause constriction of the afferent blood vessels which in turn reduce tumescence and consequently allow venous outflow. In some instances, an injection of phenylephrine may be prescribed and self administered at home which can be useful for patients where the above do not work, or for high risk individuals, particularly those living in areas where further management at the hospital is not feasible (usually in remote areas).

Patients should also be encouraged to report any side effects associated with intracavernosal injections to their prescriber to ensure the continued safety of the treatment.

#### **Further education**

Ensuring that patients are well informed and confident about intracavernosal injections and their side effects is critical to treatment success. A comprehensive instructional video on how to perform the injection, provided by leading Australian Mens Health pharmacist Brad Butt, can be found <a href="here">here</a>. Additionally, a more detailed video on priapism management can be accessed <a href="here">here</a>.

## 4.3 Topical and intraurethral administration

Alprostadil may also be used in topical and intraurethral formulations as an alternative to intracavernosal injections. <sup>16</sup>

- Topical alprostadil is applied to the urethral meatus using a cream that usually includes a permeability enhancer to facilitate the absorption of alprostadil. Once applied, it is rapidly absorbed through the collateral vessels into the spongy body and the corpus cavernosum. Doses of 200 and 300 µg are used, taking effect within 5 to 30 minutes after administration. Adverse effects include penile erythema, a burning sensation and pain, which typically resolve within two hours. Contraindications include abnormal penile anatomy, conditions that may predispose to priapism, a tendency for venous thrombosis, or hyperviscosity syndrome. Alprostadil cream should be stored in the refrigerator. 16, 34
- Intraurethral administration of alprostadil involves inserting a medicated pellet into the urethra. Although this method is considered less invasive than intracavernosal injections, it is effective in only 30–66% of patients, and some may experience pain and other adverse effects. Treatment typically begins at 500 μg and can be adjusted between 125 and 1000 μg depending on the clinical response. Correct technique is essential for efficacy, including gently rolling the penis between the hands for a few seconds after administration to help the medication coat the urethral walls. When used correctly, onset of action usually occurs within 15–30 minutes. Common side effects include local pain, dizziness and, less frequently, hypotension. Urethral bleeding and urinary tract infections may also occur.<sup>34, 35</sup>

## 4.4 Hormonal replacement therapy

After specific counsel from an endocrinologist, it may sometimes be necessary to use testosterone replacement therapy (oral, transdermal or intramuscular). These are effective but will only be used if other causes of testicular failure have been ruled out. This therapy is contraindicated for patients with a history of prostate cancer (a PSA [prostate-specific antigen] test and digital rectal examination should be performed beforehand), high hematocrit, benign prostatic hyperplasia with severe symptoms, suspicious transrectal ultrasound, severe untreated obstructive sleep apnea, uncontrolled heart failure, stroke in the last six months, or thrombophilia. Check-ups are recommended every three months for the first year, with dose adjustment and later on a case-by-case basis.<sup>36</sup>

# 4.5 Combined therapy

The use of combination therapy, typically involving an oral PDE5I alongside an intracavernosal injection agent or the addition of testosterone to a PDE5I, has been proposed as a possible treatment option for men who do not respond to monotherapy. However, this strategy carries a higher risk of adverse effects, particularly priapism. As combination therapy is currently classified as off-label use, it should be approached with caution and requires careful patient selection.<sup>41</sup>

# 5 Non-pharmacological management

Non-pharmacological approaches to ED include a range of strategies that can be highly effective, particularly for those who prefer to avoid medication or for whom pharmacological treatments are unsuitable or ineffective. These options include lifestyle modifications, psychosocial support and counselling, mechanical devices and surgical interventions, each of which addresses different aspects of ED. In addition to the physical contributors, these interventions also consider psychological, relational, and behavioural factors affecting sexual health. For many men, non-pharmacological management can lead to significant improvements in symptoms, confidence, and overall quality of life.

# 5.1 Barriers to discussing and treating erectile dysfunction

Despite the availability of effective treatment options, several barriers can prevent patients from seeking or receiving appropriate care for ED. Embarrassment and discomfort in discussing sexual health remain significant barriers, particularly when patients are reluctant to speak with a healthcare provider of a different gender. Similarly, pharmacists themselves may feel uncomfortable or unequipped to initiate conversations around ED, especially if they have not received adequate training in sexual health.

Additional barriers include misconceptions about ED, including the belief that it is a natural and irreversible consequence of ageing or that there is no effective treatment, which may further discourage patients from seeking help. Cultural differences, language barriers, financial constraints and concerns about potential side effects of treatment options also contribute to delays in care. 42

Pharmacists have an important role in overcoming these barriers. By creating a private, respectful, and non-judgmental environment for consultation, they can foster open and honest dialogue. Pharmacists should proactively address misinformation, emphasising that ED is a common and treatable condition.

Continuing professional development is essential to equip pharmacists with the confidence and knowledge to approach such conversations with empathy and effectiveness. Ultimately, building trust and maintaining a people-centred approach is essential to improving communication, adherence, and treatment outcomes.<sup>42</sup>

# 5.2 Addressing misconceptions and patient education

There is still a lot of stigma and misinformation about ED, which often delays effective treatment. It is a common but often misunderstood condition, with many men seeking quick fixes rather than addressing the underlying causes. As the most accessible healthcare providers, community pharmacists are often the first point of contact for those seeking help. This places them in a unique position to educate the public, dispel myths, and guide patients toward appropriate care pathways. By offering clear, evidence-based information, pharmacists can encourage informed decision-making and improve health outcomes.<sup>42</sup>

## 5.2.1 Common misconceptions about erectile dysfunction

There are several misconceptions about ED that contribute to inappropriate self-management of ED or the avoidance of professional help. Some of the most common misconceptions include:<sup>42</sup>

- ED is an inevitable part of ageing: Although the prevalence of ED increases with age, it is not an inevitable consequence of ageing. Many older men maintain normal erectile function, and ED is often associated with modifiable risk factors such as lifestyle choices and underlying health conditions. In addition, younger men are not immune to ED, with studies suggesting that up to 25% of men under the age of 40 experience the condition due to factors such as stress, poor lifestyle choices and psychological concerns. <sup>43</sup> Pharmacists should emphasise that ED is not an inevitable part of ageing, but rather a treatable condition that often benefits from lifestyle changes and appropriate medical care.
- ED is a permanent condition: ED is highly treatable and many men experience improvement with tailored
  interventions, including lifestyle changes such as weight loss, regular exercise and stress management. In
  addition, various treatment options, including pharmacological therapies and psychological support, can
  improve erectile function and overall well-being. Individualised treatment plans that address underlying health

conditions and behavioural factors can significantly improve erectile function.<sup>43</sup> Pharmacists should educate people about the importance of adherence to prescribed treatments and lifestyle changes, as these play a critical role in achieving long-term improvements in erectile function and overall health.

- **ED** is just a man's problem: ED can affect both partners, impacting on emotional well-being and the relationship. Open communication and, if necessary, counselling can help couples work through these challenges together.<sup>43</sup>
- **ED only affects sexual function:** ED is often a symptom of wider health problems, including cardiovascular disease, diabetes and hormonal imbalances. Its presence may be an early warning sign of systemic conditions that require medical attention.<sup>43</sup>
- ED is purely psychological: While psychological factors such as stress and anxiety can contribute to ED, a significant proportion of cases have physiological origins, including vascular insufficiency and neurological disorders.<sup>43</sup> Addressing both physiological and psychological aspects is essential for comprehensive management.
- **Dietary supplements and herbal medicines are safe and effective:** Many patients turn to unregulated supplements, herbal products or medicines of traditional health marketed for sexual health, assuming they are both safe and effective. However, these products often lack robust evidence and may contain undisclosed active ingredients that can cause harm or interact with other medicines. <sup>44</sup> Pharmacists should advise patients that a product being labelled as 'natural' does not necessarily mean it is safe. These products can cause side effects and interact dangerously with certain medicines. <sup>44</sup> It is important that pharmacists explain these risks and guide people in choosing safe and appropriate dietary supplements if they choose this type of treatment. Section 5.5 looks in more detail at the evidence and concerns surrounding these products.
- Medication is the only solution: Many people seek quick fixes, but lifestyle changes (e.g., exercise, tobacco cessation) and psychosocial interventions are equally important. Pharmacists can help shift the focus to long-term, holistic approaches.

## 5.2.2 The role of pharmacists in patient education

Pharmacists are well placed to provide education and advice on ED. Patient education plays a critical role in treatment adherence, ensuring that individuals understand the condition, its causes and the most effective management strategies. By providing patients with accurate information, pharmacists can help reduce anxiety, promote adherence to prescribed therapies and encourage healthier lifestyle choices. Their responsibilities include:

- Assessing patient concerns and guiding them towards appropriate care: Many patients who visit the pharmacy may feel embarrassed to discuss ED. Pharmacists should create a supportive environment, encourage open dialogue and ensure that they receive accurate information.<sup>3</sup>
- Provide advice on lifestyle changes: Given the strong association between ED and modifiable risk factors, pharmacists should educate patients about the benefits of regular physical activity, weight management, dietary changes, tobacco cessation, alcohol moderation, and sleep and stress management.
- Explain the risks of self-medication: Patients often seek non-prescription solutions, including unregulated dietary supplements and traditional medicines sold online. These products, typically mixtures of active ingredients, are becoming increasingly popular, particularly for conditions such as erectile dysfunction. Many of these supplements contain blends of substances that are often used at negligible doses or for which there is insufficient evidence of efficacy. 45 Pharmacists should educate patients about the potential risks of such unregulated products and emphasise the importance of relying on evidence-based treatments.
- Refer to medical consultation when needed: ED may indicate underlying health conditions that require further
  evaluation. Pharmacists should advise patients, particularly those with risk factors for cardiovascular disease
  or diabetes, to seek medical advice.
- Patient education on the correct use of ED medicines: Pharmacists also play a crucial role in educating patients on how to use ED medicines when dispensing. For example, the first dose of an intracavernosal injection should

always be supervised to ensure correct technique, increasing the likelihood of successful use at home and minimising side effects. In addition, pharmacists should provide clear guidance on how oral ED medications interact with food, as inappropriate timing or dietary considerations can reduce their effectiveness.

# 5.3 Lifestyle changes

Lifestyle changes play a crucial role in the management and improvement of erectile dysfunction, particularly in cases where vascular, metabolic, or psychological factors contribute to the condition. <sup>13, 16</sup> Regular physical activity, a balanced diet, tobacco and nicotine cessation, and weight management have been shown to improve endothelial function, improve circulation, and support overall cardiovascular health, all of which are essential for erectile function. In addition, reducing alcohol consumption, improving sleep and managing stress can further contribute to better sexual health outcomes. <sup>13</sup> These lifestyle changes not only address the underlying causes of ED, but also promote general well-being. This section outlines specific lifestyle changes that can be implemented, and Figure 4 illustrates examples of these changes.

Figure 4 – Lifestyle changes for erectile dysfunction



#### 5.3.1 Exercise

Exercise plays an important role in the management of ED, particularly by improving cardiovascular health, which is closely linked to erectile function. Regular physical activity, especially aerobic exercise, enhances blood flow, reduces arterial stiffness, and promotes healthy endothelial function, which are critical factors in achieving and maintaining an erection. Aerobic exercise, such as brisk walking, running, swimming, and cycling, improves circulation and, therefore, erectile health. He must be observed by the metabolic syndrome, or cardiovascular disease can experience significant improvements with regular exercise. A systematic review suggests that 40 minutes of moderate to vigorous intensity aerobic exercise, performed four times a week, can significantly improve erectile function. This equates to 160 minutes of exercise per week over six months and is particularly beneficial for men with ED related to physical inactivity, hypertension, metabolic syndrome, and/or cardiovascular diseases. The systematic review is a systematic review of the systematic review is a systematic review of the systema

## 5.3.2 Weight management

Weight management plays a crucial role in both preventing and improving ED in men with overweight or obesity. <sup>48</sup> Excess body weight, especially central obesity, is strongly associated with endothelial dysfunction, systemic inflammation, insulin resistance and reduced testosterone levels, all of which contribute to the onset and progression of ED. Weight loss through a combination of dietary changes, increased physical activity, and behavioural interventions can significantly improve erectile function. A review has shown that men who lose at least 5-10% of their body weight experience improvements in erectile function, with greater benefits if weight loss is maintained over the long term. <sup>49</sup> In addition, weight loss benefits cardiovascular health, reduces the risk of comorbidities such as hypertension and diabetes, and improves overall metabolic function, all of which further support erectile health. Given the strong association between obesity and ED, weight management should be considered a fundamental component of non-pharmacological treatment strategies for men with erectile dysfunction. <sup>49,50</sup>

## 5.3.3 Dietary changes

Given the strong link between diet and erectile function, a balanced, nutrient-rich diet should be considered a key strategy in the non-pharmacological management of ED (and a healthy lifestyle overall). Dietary changes support cardiovascular health, optimise metabolic function and reduce inflammation, all of which contribute to improved erectile function. Diets rich in fruits, vegetables, whole grains, lean protein and healthy fats, such as those found in the Mediterranean diet, have been associated with improved endothelial function and increased nitric oxide production, both of which are essential for healthy erections.<sup>51</sup> Including antioxidant-rich foods such as berries and leafy greens, along with omega-3 fatty acids from sources such as fish and nuts, can improve blood flow and reduce oxidative stress, promoting better erectile function.<sup>13</sup> In contrast, diets high in processed foods, refined sugars and saturated fats contribute to obesity, insulin resistance and vascular dysfunction, increasing the risk of ED. Limiting processed foods and sugary drinks also supports vascular health and hormone balance.<sup>13</sup> For a deeper understanding of how pharmacists can support nutrition and weight management to promote overall health and prevent disease, see the FIP publication Nutrition and weight management services: a toolkit for pharmacists.

## 5.3.4 Moderate alcohol consumption

Moderate alcohol consumption is an important strategy in the non-pharmacological management of ED (and a healthy lifestyle); results of a meta-analysis has shown an association between excessive alcohol consumption and erectile dysfunction. Chronic heavy drinking can disrupt hormone levels, in particular by reducing testosterone and consequently nitric oxide production, which negatively affects libido and erectile function. In addition, excessive alcohol consumption contributes to endothelial dysfunction, increased oxidative stress and nerve damage, all of which affect blood flow and the physiological mechanisms required for an erection. Reducing alcohol intake can improve vascular health, hormone balance and overall metabolic function, leading to improved erectile function and general well-being. 53

## 5.3.5 Tobacco and nicotine cessation

Tobacco cessation is an important non-pharmacological approach to managing ED, with evidence showing that quitting tobacco use can lead to both immediate and long-term improvements in erectile function. Tobacco use in any form (e.g., smoked, vaped, chewed, snuffed) is a well-recognised risk factor for ED, as it contributes to endothelial dysfunction, arterial stiffness, and impaired nitric oxide production, key factors in the vascular processes required for an erection.<sup>13</sup> Evidence suggests that the risk of developing ED increases with greater cumulative exposure to cigarette smoke. Additionally, severe ED is more commonly observed in heavy smokers, and current research indicates that in some cases, the damage may not be fully reversible even after quitting smoking.<sup>54</sup>

Smoking cessation has been shown to produce rapid and significant improvements in erectile function. Research suggests that heavy smokers can experience improved tumescence and vascular erectile response within just 24-36 hours of abstinence. Over 50% of men with erectile dysfunction (ED) who quit smoking reported improvements in erectile function after six months, which was twice the rate of those who continued to smoke. These improvements were maintained for at least a year in those who successfully quit. In patients with no other risk factors, successful smoking cessation with an eight-week course of nicotine replacement therapy led to significant improvements in erectile function that were maintained at one-year follow-up.

Electronic nicotine delivery systems (ENDS), such as e-cigarettes, are often wrongly perceived as a safer alternative to traditional tobacco products.<sup>56</sup> However, emerging evidence suggests that ENDS may negatively impact vascular health and erectile function due to the vasoconstrictive effects of nicotine and potential endothelial damage. Furthermore, the use of ENDS appears to be associated with erectile dysfunction, independent of age, cardiovascular disease, and

other risk factors.<sup>57</sup> While long-term data on the relationship between ENDS and erectile dysfunction remain limited, healthcare professionals, including pharmacists, should educate patients about the potential link between ENDS use and erectile dysfunction. They should also counsel patients on the benefits of complete tobacco and nicotine cessation to optimise erectile health and overall cardiovascular function. For more information on the health and economic impact of e-cigarette use, and the contribution of the pharmacy workforce to its elimination, visit the <u>FIP holding</u> statement on the use of electronic cigarettes.

For a deeper understanding of how pharmacists can support tobacco cessation, see the FIP publications "<u>Supporting tobacco cessation and the treatment of tobacco dependence: A handbook for pharmacists</u>" and "<u>Brief interventions for tobacco cessation: A toolkit for pharmacists</u>".

## 5.3.6 Sleep and stress management

Psychological stress is a significant contributor to erectile dysfunction (ED), as chronic stress elevates cortisol levels, which may interfere with the normal sexual response cycle in adult males. This disruption can impair testosterone production, reduce nitric oxide availability, and negatively affect vascular function, all of which are crucial for healthy erectile function.<sup>58</sup> Stress-induced anxiety creates a vicious cycle, exacerbating performance-related concerns and worsening ED. Strategies for stress management include regular physical activity, relaxation techniques such as deep breathing, progressive muscle relaxation, and mindfulness meditation. Cognitive behavioural sex therapy (CBST), which includes relaxation exercises, mindfulness (non-judgmental, present moment focus approach) and psychosexual education, has demonstrated efficacy in improving ED symptoms in young men.<sup>59</sup>

Sleep disorders, such as obstructive sleep apnoea (OSA), insomnia, shift work disorder, and restless legs syndrome, are also associated with ED. OSA causes sleep fragmentation, hypoxemia, loud snoring, breathing interruptions, awakenings due to choking, and is frequently accompanied by daytime sleepiness. These disruptions contribute to lower testosterone secretion and impaired erectile function.<sup>60</sup> Effective sleep management begins with simple lifestyle adjustments, such as maintaining a consistent sleep schedule, reducing caffeine and alcohol intake before bedtime, creating a restful sleep environment (cool, dark, and quiet), and practising relaxation techniques before sleep. Beyond these foundational strategies, behavioural interventions like cognitive-behavioural therapy for insomnia<sup>61</sup> can further enhance sleep quality, while treatments such as continuous positive airway pressure (CPAP) are particularly beneficial for patients with OSA.<sup>62</sup> Improving sleep and managing stress are essential components of a holistic approach to ED treatment.

# 5.4 Psychosocial support and counselling

Pharmacists can play an important role in providing psychosocial support and counselling in the management of ED, particularly through their direct interactions with men. By creating a non-judgmental environment and using openended questions, pharmacists can help address psychological barriers such as performance anxiety, relationship stress and feelings of shame, anxiety or low self-esteem.<sup>3</sup> Pharmacists can guide men through the emotional and mental factors contributing to ED, provide reassurance and encourage open communication with partners. Maintaining a person's confidentiality is crucial in this process, as it fosters trust and encourages individuals to seek help without fear of stigma. By providing a discreet environment, such as private consultation rooms, and safeguarding electronic health records, pharmacists can protect sensitive information and make men feel more comfortable discussing medication effects, psychological barriers or relationship issues.

While pharmacists do not directly provide therapies such as cognitive behavioural therapy or couples counselling, they play an important role in referring to these services. It is helpful for pharmacists to have access to a list of trusted contacts to whom they can refer people in need of such support. Integrating psychosocial support, such as CBST and group psychotherapy, with pharmacological treatment has been shown to improve outcomes and quality of life. <sup>63</sup> Pharmacists can collaborate with therapists to provide resources for couples counselling, mindfulness strategies and other supportive interventions that strengthen emotional relationships. This holistic approach, combining pharmacological treatment with psychosocial support, improves adherence, patient satisfaction and overall ED management.

# 5.5 Herbal and dietary supplements: evidence and concerns

Herbal extracts have been used for centuries in traditional medicine systems, such as Chinese and Indian medicine, for the treatment of ED and the improvement of sexual health. These systems include not only oral preparations but also topical formulations—such as oils, gels, and creams—that are applied externally to the penis. While many of these plants have a strong cultural and historical basis for their use, scientific evidence supporting their efficacy remains limited. In addition, the market for dietary supplements targeting male sexual dysfunction is vast, yet few well-designed clinical studies have rigorously evaluated their effectiveness. Research has shown that many herbal and dietary supplement formulations marketed for ED contain ingredients with no proven efficacy, while others include compounds that have shown promise in clinical trials but are present in amounts below the minimum effective dose, casting doubt on their real impact on sexual function. 45, 64, 65

A recent systematic review of dietary supplements marketed in Italy for ED highlighted further concerns about their composition. It found that most of these products contain complex mixtures of active ingredients, with formulations ranging from two to thirteen substances and an average of more than five per product. In particular, all 27 supplements analysed contained at least one ingredient for which there is no scientific evidence of efficacy, and 88.8% of these products contained ingredients below the minimum effective dose, raising further concerns about their actual benefits and the transparency of their marketing claims.<sup>45</sup>

This same systematic review also evaluated the clinical evidence for individual active ingredients used in these formulations. Of the 41 ingredients used in these products, 33 had no reported efficacy for ED.<sup>45</sup> However, eight ingredients had clinical evidence of efficacy, with six of these (Eurycoma longifolia, Panax ginseng, L-arginine, Corynanthe yohimbe, Tribulus terrestris and Pinus pinaster) supported by at least two randomised controlled trials. The remaining two, Crocus sativus (saffron) and Withania somnifera (ashwagandha), had only one positive reference. It is important to note that yohimbine, despite its evidence of efficacy, is not permitted to be sold as a supplement in the European Union due to safety concerns, particularly its potential to increase cardiovascular risk, as highlighted by the European Food Safety Authority.<sup>45</sup> Table 7 provides a summary of these eight active ingredients.

Table 7 – Active ingredients with evidence of efficacy for erectile dysfunction<sup>45</sup>

Herb or supplement <sup>45</sup>	Minimal effective dose/day <sup>45</sup>	Duration of treatment <sup>45</sup>	Therapeutic effects	Side effects and safety concerns
Eurycoma longifolia	200 mg	6 months	Erectile function improved and total testosterone level increased. <sup>66</sup>	Generally safe at recommended doses.
Panax (Korean) ginseng	800 mg	2 months	International Index of Erectile Function 5 (IIEF) total score, and scores on rigidity, penetration, maintenance improved. <sup>66</sup>	Panax ginseng contains several active ingredients and is generally considered safe for use for up to six months.  However, common side effects include insomnia, headache and dizziness. <sup>44</sup>
L-arginine	6000 mg	2-3 months	Significant improvement in erectile performance as assessed using IIEF-15 and IIEF-6.45	Possible side effects include abdominal discomfort, bloating, headache, insomnia and diarrhoea. L-arginine should not be taken with sildenafil. <sup>44</sup>
Corynanthe yohimbe	18 mg	2 months	Yohimbe bark contains biologically relevant alkaloids and has traditionally been used as a tonic, performance enhancer, and aphrodisiac. However, concerns exist	Despite its evidence of efficacy, yohimbine has significant safety concerns, including risks of agitation, high blood pressure, irregular heartbeat, heart attack, and seizures. It should not be used without medical supervision.44

Herb or supplement <sup>45</sup>	Minimal effective dose/day <sup>45</sup>	Duration of treatment <sup>45</sup>	Therapeutic effects	Side effects and safety concerns
			regarding its safety in food supplements. <sup>67</sup>	
Tribulus terrestris	750 mg	3 months	T. Terrestris contains steroidal saponins, which may boost testosterone and support libido and erectile function. <sup>45</sup> Studies have shown significant improvement in erectile performance as assessed using IIEF-5. <sup>45</sup>	Abdominal pain. <sup>66</sup>
Crocus sativus	30 mg	1 month	Studies have shown that erectile function, sexual satisfaction and overall IIEF scores have improved. <sup>66</sup>	Nausea, daytime drowsiness, dry mouth, nervousness, restlessness <sup>66</sup>
Withania somnifera (Ashwagandha)	600 mg	2 months	Increase serum testosterone levels. <sup>66</sup>	Generally well-tolerated in short-term use (up to 3 months).
Pinus pinaster	120 mg	3 months	Significant increase in IIEF-5 compared to control. For Pycnogenol, an extract of Pinus pinaster, helps improve ED by increasing nitric oxide production. It works with L-arginine to increase blood flow and promote vasodilation, supporting better erectile function. For Pycnogen Pycn	Not reported. <sup>65</sup>

In addition to questions of efficacy, there are significant safety concerns surrounding herbal and dietary supplements for ED. Unlike prescription medicines, these products are not subject to the same rigorous regulatory standards, leading to variability in quality, adulteration with undisclosed pharmaceutical ingredients, and inconsistencies in potency. These risks are particularly pronounced for products purchased online from unverified sources, where misleading claims and adulteration with prescription medicines, such as hidden PDE5I, have been reported.<sup>64</sup>

Given the potential variability in quality and efficacy, it is essential that individuals consult a healthcare professional before use, particularly those with underlying health conditions or those taking concomitant medications. Pharmacists should help patients navigate these options, ensuring they choose products from reputable sources and understand potential risks, interactions and limitations.

# 5.6 Medical devices for erectile dysfunction

#### 5.6.1 Vacuum erectile devices and other external devices

Among non-invasive treatments, external medical devices have proven to be useful alternatives for patients and prescribers who either prefer non-pharmacological treatments or for those patients who have contraindications to oral or injectable medications. These devices primarily include vacuum erectile devices (VEDs) with or without penile constriction rings, and in recent years, as people continue to look beyond pharmaceutical treatments, penile traction devices such as *RestoreX<sup>TM</sup>* and *PeniMaster®*, and the exo-skeleton like *Erektor* device are growing in popularity.<sup>68</sup>

#### Vacuum erectile devices

Vacuum erection devices (VEDs) are commonly used for ED treatment, particularly in men who are post-prostatectomy, or those with contraindications to oral PDE5I or injection therapy. The VED creates a vacuum around the penis, drawing blood into the corpus cavernosa, resulting in engorgement of the penile tissue. A constriction ring is then placed at the base of the penis to maintain the erection once the VED is removed. VEDs are often recommended for penile rehabilitation following prostate cancer surgery, as they can improve blood flow to the penis and prevent fibrosis, ultimately helping to preserve erectile function.<sup>69</sup>

The benefits of VEDs include their non-invasive nature, lack of systemic side effects, and the ability to provide an immediate solution to ED.<sup>70</sup> However, they come with potential drawbacks such as bruising or petechiae due to the suction process, a reduction in spontaneity due to the need to use the device beforehand as well as hinging (the effect of using a constriction ring which 'pinches' the cavernosal tissue at the pelvis and causes the penis to bend or hinge which can make penetration a little more difficult), the penis being cooler to the touch (as the blood drawn into the corpus cavernosa is approximately 60% venous and 40% arterial) and patient reports of suboptimal rigidity. Despite these disadvantages, patient satisfaction with VEDs is generally moderate to high. A 2021 study showed that 96% of patients could maintain an erection, 100% of them would recommend it to others, with 83% of their partners reporting improved sexual experiences with the device.<sup>71</sup> However, the uptake rate remains relatively low, with estimates suggesting that only about 5-10% of men with ED use a VED as a primary treatment option.<sup>72</sup>

#### Penile constriction rings

Penile constriction rings, typically used in conjunction with VEDs, are designed to maintain an erection by preventing the outflow of blood from the penis. Though effective for maintaining erections during intercourse, penile rings must be used with caution, as prolonged use (more than 30 minutes) can cause penile tissue damage or ischemia.<sup>73</sup> The advantages of penile restriction rings include their simplicity, low cost, and ease of use, which make them accessible to men who may have difficulty with oral medications or injections. However, as with VEDs, uptake is limited, and satisfaction may be compromised by discomfort, particularly when used for extended periods.

#### Erektor<sup>™</sup> device

The *Erektor*<sup>TM</sup> device, a mechanical traction device, is another option for managing ED, particularly in men where oral and injectable medications are inappropriate or contraindicated. The device applies gentle traction to the penis with one ring at the base of the penis adjacent to the pelvis and another ring behind the glans with a rigid dorsal splint holding the two opposing rings apart. This essentially stretches the penis to its full length so that it is held rigid and can be used for penetrative intercourse. There is also evidence to suggest that this can increase penile length and improve erectile function over time by stimulating collagen production and increasing blood flow. Although evidence on the long-term satisfaction rates and efficacy of the *Erektor* device are still emerging, patient feedback at this point in time suggests it is a promising alternative, non-pharmacological management option.

#### **Traction devices**

Penile traction devices such as *RestoreX<sup>TM</sup>* and *PeniMaster®* work by applying a gentle, continuous stretching force to the penis, which can potentially improve penile length and girth over time. These devices are particularly useful for men with Peyronie's disease or those wishing to address post-surgical ED. Research has shown that penile traction can improve penile length and curvature, especially when used for several hours a day over an extended period.<sup>75</sup> The benefits of traction devices are largely related to tissue regeneration and improvement in erectile function without the need for invasive procedures. However, their prolonged use is a major disadvantage, and patient satisfaction can vary depending on individual commitment and outcomes.<sup>76</sup>

## 5.6.2 Penile prostheses

Penile implants, also known as penile prostheses, are a well-established and highly effective treatment option for men with ED, particularly in those who have not responded to pharmacological therapies or non-invasive devices. Penile implants are surgically inserted into the penis to provide a permanent solution for achieving an erection. This treatment is often considered for men with severe ED, including those with diabetes, neurological conditions, or post-surgical ED,

such as following prostate cancer treatment. The main types of penile implants include inflatable implants, malleable (semi-rigid) implants, and newer innovations such as inflatable implants with antimicrobial coatings designed to reduce the risk of infection.

## Mechanism of action and types of implants

Penile implants work by mechanically providing support to the penis to allow for the achievement of an erection. Inflatable penile implants consist of a pump, a reservoir, and two cylinders that are inserted into the penis. When the pump is activated, fluid is transferred into the cylinders, causing the penis to become erect. Malleable implants, on the other hand, consist of bendable rods that provide rigidity to the penis. While inflatable implants are considered to offer a more natural appearance and function, malleable implants are simpler, require less maintenance, and are less prone to mechanical failure.<sup>77</sup>

#### Satisfaction rates and outcomes

Penile implants are known for their high satisfaction rates, with several studies reporting success rates of 90% or higher. Satisfaction is often related to both functional outcomes (i.e., the ability to achieve an erection) and psychological factors (i.e., regaining a sense of masculinity and sexual function). A study by Seob Ji *et al.* reported that nearly 90% of patients were satisfied with their implants, with a significant improvement in quality of life and relationship satisfaction post-surgery. Notably, sexual partners of patients with penile implants also report high levels of satisfaction due to the increased sexual spontaneity and reliability of the device.

# 5.7 Other emerging treatments

Several novel therapies for ED are currently under investigation. While some early findings have shown modest or short-term benefits, it is important to note that these treatments remain experimental and are not yet recommended as standard care. Pharmacists should be aware of these options to address patient queries accurately, but must emphasise the limited evidence base, uncertain long-term efficacy, and the need for specialist oversight.

**Melanocortin receptor agonists**: These are centrally acting agents that have demonstrated promise in initiating erections without the need for sexual stimulation, particularly in individuals who do not respond to phosphodiesterase type 5 inhibitors. These agents function by modulating central nervous system pathways to enhance erectile function.<sup>80</sup>

**Low-intensity extracorporeal shock wave therapy (LI-ESWT)**: This is a non-invasive treatment that uses low-intensity shock waves to promote tissue regeneration and improve blood flow within the penile tissues. This therapy has shown potential in repairing organic damage to the corpora cavernosa, offering a restorative approach to ED management.<sup>81</sup>

**Gene and cellular-based therapies**: Emerging gene and cellular-based therapies aim to address ED at the molecular level by enhancing specific cellular and enzymatic functions. These approaches seek to mitigate or reverse the underlying causes of ED, providing a more fundamental solution compared to symptomatic treatments.<sup>82</sup>

**Nerve transplantation**: A surgical procedure where a healthy nerve from another part of the body (usually the leg) is used to repair the damaged cavernous nerve, often caused by prostate cancer surgery. The procedure aims to restore erectile function by essentially "bridging" the damaged nerves with the transplanted nerve tissue. Studies have shown that nerve grafting can improve erectile function in a significant portion of patients, with some studies reporting success rates around 70%. However, this is still an area of much research at the time of writing, with patient uptake at this stage relatively low.<sup>83</sup>

Platelet-rich plasma (PRP) injections: Another emerging treatment for ED with a growing evidence base. PRP is derived from a patient's own blood and contains a high concentration of growth factors that may promote tissue regeneration and improve erectile function. Preclinical studies have demonstrated that PRP can enhance erectile function in animal models by promoting angiogenesis and neuroregeneration. Clinical studies have reported improvements in erectile function scores among men receiving PRP therapy, with minimal adverse effects. However, while these findings are encouraging, further large-scale, randomised controlled trials are necessary to establish standardised treatment protocols and confirm the long-term efficacy and safety of PRP injections for ED.<sup>84</sup>

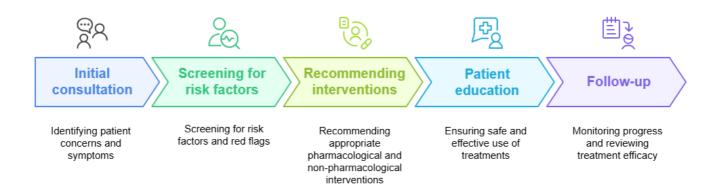
**Botulinum toxin type A (BoNT-A): BoNT-A** has been studied as a potential treatment in cases of ED unresponsive to conventional treatments. The proposed mechanism involves BoNT-A's ability to inhibit the release of neurotransmitters like norepinephrine, leading to relaxation of cavernosal smooth muscle and improved penile blood flow. Preliminary studies have shown promising results. For instance, a retrospective analysis reported that 50% of men with ED unresponsive to PDE5Is or prostaglandin E1 intracavernosal injections achieved a clinically meaningful improvement in erectile function after receiving intracavernosal BoNT-A injections, with effects lasting up to six months and minimal adverse events. Whilst the early evidence is largely positive, there is more research and study to be undertaken before BoNT-A injections become widely adopted.

The growing number of emerging therapies reflects ongoing interest in ED treatment. However, these options remain under investigation and should be considered only under specialist supervision, with careful attention to potential side effects, contraindications, efficacy, and cost.

# 6 Managing erectile dysfunction in the pharmacy: a people-centred approach

Pharmacists play a crucial role in the management of ED through a structured, people-centred approach. By identifying concerns, screening for risk factors, recommending tailored interventions, and ensuring proper education and follow-up, the pharmacist can help achieve better outcomes. Figure 5 summarises the key steps pharmacists should follow when managing erectile dysfunction in the pharmacy, with further details on each step provided below.

Figure 5 – Steps for managing erectile dysfunction in the pharmacy



### Step 1 - Initial consultation: Identifying patient symptoms and concerns

The initial consultation sets the foundation for effective management of ED. Pharmacists should aim to create a comfortable and open environment to ensure that the patient feels safe and supported in discussing personal concerns and symptoms. This step also provides an opportunity to start conversations about broader aspects of sexual health, encouraging open dialogue and reducing stigma. To help patients feel at ease, pharmacists should begin by explaining that some of the questions may be personal and are necessary to ensure the medicine is right for them. This approach will help to foster trust and understanding.

It is essential that pharmacists approach this conversation with professionalism, confidence, and care, ensuring they do not convey any hesitation or embarrassment. This can be achieved by framing questions in a sensitive, non-intrusive manner. Instead of asking only closed questions, pharmacists should aim for a mix of open-ended questions, which will engage the patient and encourage a more in-depth response.

The primary aim of this step is to gather information about the patient's concerns and symptoms, determine the nature of the problem and identify any underlying conditions. Pharmacists should ask clear, open questions that allow patients to express themselves fully, such as: "Can you tell me more about what you're experiencing?" or "How have you been feeling in terms of intimacy with your partner?" These types of questions will help to create a more conversational, rather than inquisitorial, approach.

Table 8 provides a list of example questions that pharmacists may use to assess a male patient's concerns and symptoms related to ED. These questions are designed to be adaptable to each case, with a focus on creating a supportive and non-judgmental environment. It is important that the pharmacist tailors these questions to the individual patient, ensuring that the approach remains respectful and considerate of their feelings.

Additionally, pharmacists should advise patients that some of the questions might be sensitive in nature, but they are crucial for determining the most appropriate treatment. Furthermore, the use of a private consultation room is essential for maintaining confidentiality and helping the patient feel at ease. Training pharmacy support staff on how to handle requests for OTC medications and referrals to the pharmacist is also key to providing a supportive and professional service.

## Table 8 – Example of questions to engage individuals and explore ED-related concerns <sup>3</sup>

#### Example questions pharmacists can use to engage individuals and explore ED-related concerns

- Do you experience sexual desire?
- Do you want to engage in sexual intercourse?
- Are you experiencing intimacy problems with your partner?
- Do you have difficulty achieving and maintaining erections?
- How often do you achieve an erection?
- Do you experience erections during sleep, while dreaming, or in the mornings?
- Are your erections firm enough to achieve penetration?
- Do you have problems reaching a climax?
- Do you have problems ejaculating?
- Do you experience anxiety when thinking about intercourse?
- Are there times when your ED is worse? If so, in which situations?
- Have you noticed a decreased pleasure in life?
- Are you happy with your sexual partner?
- Do you have a good relationship with your sexual partner?
- When did this problem begin? Was it abrupt or gradual?
- How has ED affected your sex life?
- Are you or your partner angry about this situation?

## Step 2 - Screening for risk factors and red flags

Once the pharmacist has gained an understanding of the patient's symptoms and concerns, the next step is to assess potential risk factors or red flags that may indicate underlying conditions such as cardiovascular disease, diabetes, or neurological disorders. ED can be a sign of such conditions, and it is crucial for the pharmacist to identify any serious health issues that may require further medical investigation, intervention, or specialist referral. To screen for these, the pharmacist should ask targeted questions, and where possible, perform POCT for vital signs, blood glucose, and lipid levels. These tests can provide immediate insights into a patient's cardiovascular and metabolic health, supporting timely decision-making and appropriate referrals. Additionally, given the potential association between ED and prostate problems, screening for genitourinary health issues is also important.

It is equally important to obtain a comprehensive social history, including information about tobacco and alcohol consumption, physical activity levels, and other lifestyle habits, as these factors can affect sexual function. Furthermore, the pharmacist should screen for possible medicine-induced erectile dysfunction.<sup>3</sup> For more information on medications that may contribute to ED, refer to section 2.6.4. To screen for these conditions and contributing factors, the pharmacist may ask the questions listed in the following table and, where applicable, conduct POCT to support their decision-making.

Table 9 provides examples of questions the pharmacist may ask during the conversation to identify potential risk factors or any red flags that may require referring the patient to a physician or a specialist.

Table 9 – Example of screening questions for known causes of ED  $^{\rm 3}$ 

Example of screening questions	Suggested actions for the pharmacist
Have you ever been diagnosed with diabetes, high blood pressure, high cholesterol, or depression?	These are common risk factors for ED. Confirm if the condition is controlled and refer to a physician if not under appropriate care.
Do you have any history of disease, for example involving the heart, blood vessels, nerves, liver or kidneys?	Consider referral to a physician for further investigation.
Are you currently taking any medications, particularly those for hypertension, diabetes, or depression?	Review for possible medicine-induced ED (see section 2.6.4). Consider discussing alternative therapies with the prescriber if appropriate.

Example of screening questions	Suggested actions for the pharmacist	
Have you ever been prescribed any nitrate medicine used to treat or prevent chest pain (angina), heart attack or heart failure?	Important safety alert: PDE5 inhibitors are contraindicated with nitrates. Do not recommend treatment and refer to a physician.	
Are you experiencing any changes in your appetite, thirst, urinary patterns, or weight?	May indicate underlying endocrine or metabolic disorder. Refer for further medical evaluation.	
Have you ever had urogenital trauma or surgery?	Can affect erectile function. Assess timeline and consider referral if related to current symptoms.	
Have you ever been diagnosed with prostate problems?	Prostate conditions may contribute to ED or urinary symptoms. Consider referral or further assessment.	
Do you have Peyronie's disease or any other condition causing a change in the shape of your penis?	Pharmacists should not recommend OTC treatment. Refer to a specialist.	
Do you experience any problems with urinary voiding? Do you experience urgency, frequency, straining, hesitancy, incomplete bladder emptying, or a weak urine stream?	May indicate prostate enlargement or infection. Refer to a physician for further evaluation.	
Do you smoke or use any tobacco products?	Explain that tobacco use is a modifiable risk factor for ED.  Provide brief tobacco cessation advice and support (see section 5.3.5).	
Do you drink alcohol?	Excessive alcohol use can contribute to ED. Offer lifestyle advice and assess for alcohol misuse if necessary (see section 5.3.4).	
Do you use recreational drugs such as marijuana, cocaine, or heroin?	Some substances can negatively affect sexual function. Consider harm reduction advice and, if appropriate, referral to support services.	
How active are you throughout the day? Do you engage in regular aerobic exercise?	Low physical activity is a modifiable risk factor. Encourage increased activity as part of ED management (see section 5.3.1).	
What are your hobbies? Do you routinely ride bicycles, motorcycles, or horses? Do you take regular cycling classes at the gym?	Prolonged perineal pressure may contribute to ED. Consider suggesting adjustments to habits if relevant.	

## Step 3 - Recommending appropriate interventions

Following the initial consultation and screening, pharmacists can recommend suitable pharmacological and non-pharmacological interventions (see Chapters 4 and 5), in accordance with local and national regulations. These recommendations should be guided by the patient's clinical needs and personal preferences, as explored during the consultation. Table 10 outlines examples of questions pharmacists may ask to better understand these preferences and needs.

Table 10 – Example questions to support tailored intervention recommendations

#### **Example questions**

- Have you tried any treatments for ED in the past (e.g., medicines, devices, or counselling)?
- Are you open to making lifestyle changes, such as improving your diet or exercise routine?
- Do you have any concerns or preferences about medication (e.g., side effects, administration)?
- Do you have any allergies or intolerances?

In countries where the supply of PDE5Is without a prescription is permitted (e.g., under pharmacist-led prescribing), pharmacists have a vital role in ensuring the safe and appropriate use of these medicines. Pharmacists must conduct a thorough consultation to assess the patient's suitability for treatment. 86-88 This includes:

- Confirming the presence of ED and ensuring the indication for PDE5I use is appropriate.
- Assessing for any contraindications (e.g., recent myocardial infarction, stroke, anatomical abnormalities).

- Identifying concomitant health conditions or medications that may increase risk or interact with treatment.
- Using risk minimisation tools such as pharmacy checklists or patient questionnaires to support consistent and safe decision-making.

For first-time users, these checks are critical to establishing whether referral to a physician is needed before supply. For repeat users, pharmacists should ask about side effects, treatment response, and any changes in medical status or medications since the last supply. 86, 88

Clear counselling should be provided to all patients regarding the correct use of PDE5Is, what to expect in terms of outcomes, how to manage side effects, and when to seek further medical advice. Additionally, pharmacists should reinforce the importance of lifestyle factors such as diet, exercise, stress reduction, and overall health in supporting ED management and well-being, as described in the following steps.<sup>87</sup>

#### Step 4 - Patient education: Ensuring safe and effective use of treatments

After identifying treatment options, patient education is crucial to ensure the safe and effective use of recommended interventions. This includes providing information on the correct use of medications or devices, discussing potential side effects, and addressing any concerns the patient may have. This is also essential to ensure treatment adherence, which is key to achieving the desired effectiveness.

Using a people-centred approach, pharmacists should ensure that the patient understands the treatment plan to support adherence and optimise outcomes. Based on the patient's responses and any concerns, the pharmacist can determine whether further clarification, reassurance, or follow-up is needed. If the patient expresses confusion, hesitation, or reports adverse effects, treatment adjustments (in collaboration with the prescriber) or referral may be appropriate. Scheduling follow-up consultations can further support ongoing adherence and treatment effectiveness. Table 11 provides examples of key pointers and questions to support treatment adherence.

Table 11 – Key patient education points and questions to support treatment adherence

Key patient education points	Key questions to support treatment adherence
<ul> <li>Explain how the pharmacological treatment works and its expected benefits (see Chapter 4).</li> <li>Discuss proper dosing, administration, and timing for medications (e.g., PDE5I) or devices (e.g., vacuum erection devices) (see Chapter 4).</li> <li>Highlight any potential side effects and what the patient should do if they occur (see Chapter 4).</li> <li>Emphasise the importance of adhering to the recommended lifestyle changes to improve sexual and overall health (see Chapter 5).</li> <li>Encourage open communication with the patient's partner to increase the effectiveness of treatment and maintain a positive sexual relationship.</li> </ul>	<ul> <li>Do you understand how to use the pharmacological treatment or device?</li> <li>Do you have any concerns or questions about potential side effects?</li> <li>How comfortable are you with the lifestyle changes necessary to improve your condition?</li> <li>Is there anything else you would like to know more about the treatment or condition?</li> </ul>

#### Step 5 - Follow-up: monitoring progress and reviewing treatment efficacy

Follow-up is essential to assess the progress of treatment and to determine whether interventions are achieving the desired outcomes. Pharmacists should regularly monitor the patient's response to therapy and address any challenges or concerns that may arise. This includes assessing both the physical and psychological effects of treatment.

Some manufacturers may provide patient supply cards, which can be presented by the patient at the pharmacy. These cards serve as a prompt for the pharmacist to monitor the patient's progress, review treatment efficacy, and assess the need for further supplies.

If the treatment is not achieving the desired results or if the patient is experiencing adverse effects, the pharmacist should consider adjusting the treatment plan accordingly. In cases where therapy proves ineffective or the patient's condition worsens, the pharmacist must promptly refer the patient to their physician for further evaluation and possible alternative interventions. This collaborative approach ensures that the patients receive optimal care tailored to their individual needs.

Regular follow-up allows the pharmacist to ensure that the treatment plan remains effective and that the patient is satisfied with the results. It also provides an opportunity to identify any issues early and make any necessary adjustments.

The following table provides examples of questions the pharmacist may ask during follow-up to ensure the patient's continued progress and to support adherence.

#### Table 12 – Examples of follow-up questions to assess treatment progress<sup>86</sup>

#### Examples of follow-up questions to assess treatment progress

- How has your treatment worked for you so far? Have you noticed any improvement in your ED symptoms?
- Are you experiencing any new side effects or difficulties with your treatment?
- Have any lifestyle changes had a positive impact on your sexual health and general well-being?
- Is there anything you would like to change in your treatment plan to improve results?

# 7 Pharmacists' professional and ethical responsibilities in ED management

Pharmacists play a pivotal role in the ethical, safe, and effective management of ED. Their responsibilities extend beyond dispensing medications to encompass clinical judgement, public health stewardship, and interprofessional collaboration. The following key areas outline pharmacists' core responsibilities in the context of ED.

## Professional competence and people-centred care

Pharmacists must apply evidence-based knowledge and clinical competence to assess, counsel, and support individuals experiencing ED. Care should be people-centred—respecting individual needs, preferences, and values—while promoting shared decision-making and continuity of care.

Clear communication, sensitivity to stigma, and cultural awareness are vital in ensuring patients feel safe and supported. Pharmacists must address misconceptions, explain the appropriate use of ED treatments, and provide realistic guidance to manage expectations. They also play a critical role in identifying when ED may indicate underlying health conditions (e.g., cardiovascular disease, diabetes, or depression) and ensuring timely referrals for medical evaluation.

## Interprofessional collaboration

Pharmacists should actively engage with general practitioners, urologists, endocrinologists, cardiologists, and mental health professionals to ensure coordinated, holistic care. ED is often multifactorial, requiring a multidisciplinary approach to address comorbidities and psychosocial aspects.

The <u>FIP policy on interprofessional collaborative practice</u> highlights the pharmacist's role in improving access to treatment, enhancing care continuity, and supporting patient involvement in health decisions.<sup>89</sup> Effective collaboration requires recognising the roles and expertise of all team members, fostering mutual respect, and using clear, timely communication—including digital tools—to support shared care and appropriate referrals.

#### Safety considerations and appropriate prescribing

In settings where PDE5Is like sildenafil and tadalafil are available without a prescription through pharmacy, pharmacists have a responsibility to ensure safe and appropriate supply. They must assess whether the patient meets eligibility criteria, taking into account:

- Diagnosis of ED and intended use (not for recreational purposes);
- Contraindications (e.g., cardiovascular risks, recent MI or stroke, anatomical abnormalities);
- Interacting medications (e.g., nitrates, alpha-blockers);
- Changes in health status or medication since previous use.

Pharmacists should tailor their consultations based on whether the individual is a first-time or repeat user, reassessing safety, treatment effectiveness, and potential side effects accordingly.

Comprehensive counselling should be provided on treatment use, timing, effectiveness, and common side effects. Inappropriate or unsafe use must be prevented, particularly in cases where ED may signal a more serious health issue. In such cases, pharmacists must recognise red flags and refer patients for medical evaluation.

Consultations must respect patient privacy and be delivered with professionalism and empathy.

## Supply chain integrity and public health considerations

#### Substandard and falsified medications and illicit supply

In some regions, despite legal restrictions, ED medications continue to be sold without a prescription, raising significant concerns about inappropriate use and unregulated supply chains. <sup>92</sup> The rise of online sales of ED medications has led to an alarming increase in falsified and unregulated products, <sup>39, 93</sup> posing serious public health risks. <sup>94</sup> Many men, due to stigma or convenience, obtain treatments online, exposing themselves to unverified substances that may be ineffective or harmful.

## Pharmacists must:39,95

- Educate patients about the risks of buying medicines from unverified sources;
- Direct individuals to licensed and accredited suppliers;
- Monitor and report suspected adverse reactions from online purchases;
- Encourage patients to report any side effects and seek medical help if needed;
- Guide patients on how to identify legitimate products and report suspected counterfeits;
- Support public awareness campaigns on the dangers of falsified ED products.

By championing responsible sourcing and reporting concerns, pharmacists act as frontline protectors of medicine quality and patient safety.

## Health education and advocacy

Pharmacists have an advocacy role in correcting misconceptions and countering misleading advertising related to ED treatments, whether pharmaceutical or alternative (e.g., supplements, herbal products).<sup>96</sup>

## They should:97

- Provide accurate, evidence-based information;
- Caution against recreational or off-label use of ED medicines;
- Address unrealistic expectations promoted by mass marketing;
- Promote professional consultation and discourage self-medication;
- · Educate the public on critically evaluating online health content;
- Report misleading advertisements and support regulatory compliance.

By reinforcing the importance of holistic, evidence-based care, pharmacists empower individuals to make informed choices and safeguard the integrity of health information in the public sphere.

# 8 Conclusions

Erectile dysfunction is a complex condition that has a significant impact on individuals' physical, emotional and psychosocial health. Pharmacists have an important role to play in the management of ED, not only by delivering evidence-based pharmacological treatments but also by promoting lifestyle changes and offering emotional support. A people-centred approach, alongside interprofessional collaboration, is essential for the effective management of ED and the improvement of people outcomes.

This handbook serves as a comprehensive and practical resource, equipping pharmacists with the knowledge required to provide high quality care, encompassing both pharmacological and non-pharmacological approaches. By integrating these approaches into daily practice, pharmacists can make a significant difference to the lives of those affected by ED, promoting holistic health and reducing the stigma associated with the condition.

Furthermore, as treatment options and approaches to ED management continue to evolve, it is essential that pharmacists engage in continuing professional development. Participation in continuing education programmes, workshops and interprofessional collaboration allows pharmacists to stay updated with the latest evidence and clinical practices, ensuring increasingly effective and personalised care.

Legislators and regulators can improve people's choice and access to ED treatments and lessen the burden on the wider healthcare network by harnessing the unique position of pharmacists through expanding their scope to encompass pharmacy-based care options.

With the guidance and strategies outlined in this handbook, pharmacists are well placed to play a crucial role in the management of erectile dysfunction by providing accessible, effective care tailored to the needs and preferences of the patient. By adopting a people-centred approach and working in collaboration with other healthcare professionals, pharmacists can help reduce the burden of erectile dysfunction and its associated comorbidities, improve individuals' quality of life, and contribute to the overall effectiveness of the healthcare system.

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