Medicines Adverse Reactions Committee

Meeting date	10/09/2026	**Agenda item**	3.2.2
Title	**Sexual side effects with SSRIs and venlafaxine**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For advice

Active ingredient	**Product name**	**Sponsor**
Citalopram	**Celapram**	Viatris Limited
Citalopram	Cipramil	Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
Escitalopram	**Ipca-escitalopram**	Ipca Pharma (NZ) Pty Limited
Escitalopram	Lexapro	Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
Escitalopram	Loxalate	Viatris Limited
Fluoxetine	**Arrow Fluoxetine (capsule)**	Teva Pharma (New Zealand) Limited
Fluoxetine	Arrow Fluoxetine (dispersible tablet)	Teva Pharma (New Zealand) Limited
Fluoxetine	Fluox capsule	Viatris Limited
Fluoxetine	**Fluox dispersible tablet**	Viatris Limited
Paroxetine	Aropax	GlaxoSmithKline NZ Limited
Paroxetine	**Loxamine**	Viatris Limited
Paroxetine	Paxtine	Viatris Limited
Sertraline	**Setrona**	Douglas Pharmaceuticals Limited
Venlafaxine	**Efexor XR**	Viatris Limited
Venlafaxine	Enlafax	Viatris Limited

Products with a published data sheet. Additional products are approved but not available.

PHARMAC funding	Products funded by PHARMAC are highlighted in **bold**.
Previous MARC meetings	*September 2019*: Serotonin reuptake inhibitor and persistent sexual dysfunction *June 2026*: Update on sexual dysfunction (post SSRI sexual dysfunction, PSSD) following discontinuation of serotonin reuptake inhibitors
International action	See section 5.
Prescriber Update	Sexual dysfunction associated with antidepressants and antipsychotics (*Prescriber Update 36(1): 5-7 March 2015*)
Classification	Prescription medicine
Usage data	Refer to Annex 1, section 2.1.2.
Advice sought	**The Committee is asked to advise:** • Whether the same sexual side effects (including gender-specific effects) should be listed in section 4.8 of the data sheets for all SSRIs and venlafaxine.

	• Whether all the sexual side effects listed in the data sheets for SSRIs and venlafaxine could be long-lasting after treatment discontinuation. • Whether a warning regarding sexual side effects should be the same in section 4.4 of the data sheets for all SSRIs and venlafaxine. • Whether any communication is required other than in MARCs remarks?

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1 PURPOSE

At the June 2026 Medicines Adverse Reaction Committee (MARC) meeting, Medsafe sought advice from the Committee in relation to sexual dysfunction with selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs), in particular, about symptoms that continue or occur following discontinuation of treatment (post-SSRI sexual dysfunction (PSSD)) [1]. The report presented to the MARC is available in Annex 1.

The Committee were asked whether the information in the data sheets for SSRIs/SNRIs for sexual dysfunction was sufficient to manage this risk and on the strength of evidence for an association between SSRIs/SNRIs and the syndrome PSSD. The minutes of the meeting are published on the Medsafe website [1].

The Committee considered that there would be benefit in reviewing the specific symptoms of sexual dysfunction reported with SSRIs/SNRIs, including whether they continue following discontinuation of treatment. The Committee would then consider whether specific symptoms of sexual dysfunction can be more clearly defined in the data sheet [1].

The purpose of this report is to provide the additional information sexual side effects with SSRIs and SNRIs (venlafaxine) requested at the previous meeting.

2 BACKGROUND

2.1 Sexual dysfunction

Sexual function is the result of biological, psychological, interpersonal and social factors working together [2].

A particular difficulty experienced during any stage of the sexual response cycle may cause adverse sexual symptom(s) [2].

A pattern of symptoms that may be persistent or symptoms that cause a significant problem with sexual functioning can be grouped under the umbrella term ‘sexual dysfunction’ [2,3].

A formal diagnosis of sexual dysfunction can be made when criteria for a specific disorder are met within a recognised diagnostic system such as the DMSR—5-TR. This includes presence of sexual problems with clinically significant distress that cannot be fully attributable to another cause and are present for typically at least 6 months [2,3].

2.1.1 Types of sexual dysfunction

The main types of sexual dysfunction correspond to symptoms that occur within the domains of sexual functioning [2,3,4].

Table 1 provides an overview of sexual problems that may occur within the major domains. More than one symptom may present simultaneously, and symptoms may occur across different domains [2,3,4].

Table 1: Examples of domains of sexual function and types of symptoms that may occur

Domain of sexual function	Example symptoms
Desire	Reduced libido, loss of sexual interest, fewer sexual thoughts
Arousal	Erectile dysfunction, lubrication difficulties, impaired arousal, reduced genital response
Orgasm	Delayed orgasm, anorgasmia, reduced orgasm intensity
Ejaculation (male specific)	Delayed ejaculation, absent ejaculation, premature ejaculation
Sexual pain	Dyspareunia, genito-pelvic pain, genital pain during sexual activity
Sexual satisfaction	Reduced pleasure or satisfaction from sexual activity, decreased sexual fulfilment

Source: Adapted from:

- Lori A Brotto, Sandrine Atallah, Joana Carvalho, Elisabeth Gordon, Patrícia M Pascoal, Mona Reda, Kyle R Stephenson, Inês M Tavares, Psychological and interpersonal dimensions of sexual function and dysfunction: recommendations from the fifth international consultation on sexual medicine (ICSM 2024), *Sexual Medicine Reviews*, Volume 13, Issue 2, April 2025, Pages 118–143, https://doi.org/10.1093/sxmrev/qeae073 (accessed 5 August 2026).
- Bhugra D, Colombini G. Sexual dysfunction: classification and assessment. *Advances in Psychiatric Treatment*. 2013;19(1):48-55. doi:10.1192/apt.bp.112.010884 (accessed 7 August 2026).
- Trost L, Rowland D, Meston C, Kingsberg S, Briken P, Gross M, Esho T, Lewis R, Giraldi A. Definitions, classification, and epidemiology of sexual dysfunction: a consensus statement from the Fifth International Consultation on Sexual Medicine 2024. Sex Med Rev. 2026 Apr 1;14(2):qeag028. doi: 10.1093/sxmrev/qeag028. PMID: 42149688. (accessed 6 August 2026).

2.1.1.1 Male and female sexual dysfunction

The type and patterns of sexual problems in males and females can differ [5]. This section further categorises sexual symptoms by the main types of sexual dysfunction experienced by each gender (Table 2 and Table 3) [5].

Women may more commonly experience impairments of desire and arousal, whereas men may more commonly experience erection dysfunction and premature ejaculation [5].

Women may be more likely to experience problems across multiple domains of sexual function simultaneously, whereas in men, problems are more likely to occur with a particular aspect of sexual functioning [5].

The presentation of sexual problems can also vary with age. In men, erectile dysfunction becomes more common with age, while women may experience changes in desire, arousal, lubrication and sexual pain [6].

<u>Male sexual dysfunction</u>

The three main general categories of male sexual dysfunction include erectile dysfunction (ED), diminished libido and ejaculatory disorders (Table 2) [7,8].

Table 2: Main general types of male sexual dysfunction

Type of sexual dysfunction	Additional information
Erectile dysfunction (ED)	Defined as the consistent or recurrent inability to acquire or sustain an erection of sufficient rigidity and duration for sexual intercourse. ED is the most common type of sexual dysfunction in men.
Decreased libido	Defined as a reduced interest or desire in sexual activity. Men with ED may experience loss of libido as a secondary consequence of ED.
Ejaculatory disorders	A heterogeneous group of disorders that include premature, delayed and retrograde ejaculation and anorgasmia.

Source: Adapted from:

- Rosen & Khera. 2026. Epidemiology and etiologies of male sexual dysfunction. *UpToDate*. 31 Oct 2024. URL: https://www.uptodate.com/contents/epidemiology-and-etiologies-of-male-sexual-dysfunction (accessed 15 July 2026).
- Khera. 2026. Evaluation of male sexual dysfunction. *UpToDate*. 2 Jan 2026. URL: https://www.uptodate.com/contents/evaluation-of-male-sexual-dysfunction (accessed 15 July 2026).

Female sexual dysfunction

Female sexual dysfunction takes different forms, including lack of sexual desire, impaired arousal, inability to achieve orgasm or pain with sexual activity [9].

Table 3 includes the major general categories for sexual dysfunction in females.

Table 3: Main general types of female sexual dysfunction

Type of sexual dysfunction	Additional information
Female sexual interest/arousal disorder	Lack of, or significantly reduced, sexual interest/arousal, as manifested by at the absence or reduction of at least three of the following: • interest in sexual activity • sexual/erotic thoughts or fantasies, • initiation of sexual activity (and typically unreceptive to a partner's attempt to initiate) • sexual excitement/pleasure during sexual activity • sexual interest/arousal in response to any internal or external sexual/erotic cues, • genital or non-genital sensations during sexual activity
Female orgasmic disorder	Presence of either of the following symptoms and experienced on almost all or all occasions of sexual activity: • Marked delay, infrequency or absence of orgasm • Markedly reduce intensity of orgasmic sensations
Genitopelvic pain/penetration disorder	Persistent or recurrent difficulties with one (or more) of the following: • Vaginal penetration during intercourse • Marked vulvovaginal or pelvic pain during vaginal intercourse or penetration attempts • Marked fear or anxiety about vulvovaginal or pelvic pain in anticipation or, during or as a result of vaginal penetration • Marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration

Type of sexual dysfunction	Additional information
Other sexual dysfunction	Symptoms characteristic of a sexual dysfunction that cause clinically significant distress in the individual predominate but do not meet the full the full criteria for any of the disorders in the sexual dysfunction diagnostic class.
Unspecified sexual dysfunction	Symptoms characteristic of a sexual dysfunction that cause clinically significant distress in the individual predominate but do not meet the full the full criteria for any of the disorders in the sexual dysfunction diagnostic class and there is insufficient information to make a more specific diagnosis.

Source: Adapted from Shifren 2026. Overview of sexual dysfunction in females: Epidemiology, risk factors and evaluation. *UpToDate*. 16 December 2025. URL: https://www.uptodate.com/contents/overview-of-sexual-dysfunction-in-females-epidemiology-risk-factors-and-evaluation (accessed 15 July 2026).

Comments

Many modern definitions of sexual dysfunction require clinically significant distress or impairment and not only a change in sexual function or presence of symptoms for diagnosis. However, sexual problems are still common without a meeting formal diagnosis criterion for a sexual dysfunction disorder.

There are many factors that influence sexual functioning in general such as sex, age, comorbidities, psychiatric disorders, psychosocial factors and medicines. Sexual function also naturally varies depending on circumstances in relationships, stress, age and gender.

Sexual functioning should be understood within an individual's biopsychosocial context, as experiences of sexual dysfunction are often highly individual and not solely physical or psychological in origin.

2.2 Sexual dysfunction and psychiatry disorders

2.2.1 Background

Sexual dysfunction has a strong connection with psychiatric disorders such as depression, anxiety, schizophrenia, Post Traumatic Stress Disorder (PTSD) and bipolar disorder [10].

Research suggests that individuals with psychiatric conditions are more likely to experience sexual dysfunction compared to the general population [10].

The relationship between sexual dysfunction and psychiatric disorders is complex, involving a range of mechanisms that can affect sexual functioning at various levels. Various domains may be affected [10].

The connection is bidirectional, meaning that sexual problems can exacerbate mental health conditions, while the mental health condition itself can contribute to sexual difficulties [10].

Assessment of sexual dysfunction in patients with psychiatric disorders requires a comprehensive, multifaced approach as it involves psychological and physiological factors [10].

2.2.1.1 Potential mechanisms

Neurobiological mechanisms that are thought to impact sexual functioning in psychiatric disorders involve alterations in brain function, neurotransmitter imbalances and hormonal changes [10].

Neurotransmitters such as serotonin, dopamine and norepinephrine are key regulators in sexual behaviour and mood. High levels of serotonin are associated with decreased libido, delayed ejaculation and difficulty in achieving orgasm. Reduced levels of dopamine activity may result in diminished sexual motivation and arousal. Norepinephrine has a role in sexual arousal and mood regulation [10].

In women, alternations in oestrogen and progesterone levels can affect libido and sexual arousal. In men, low testosterone levels may contribute to erectile dysfunction and reduced sexual drive. Changes in prolactin levels may affect orgasm and erections [10].

2.2.2 Prevalence and types of sexual dysfunction in psychiatric disorders

2.2.2.1 Depression

Depression is strongly linked to various types of sexual dysfunction including reduced libido, delayed orgasm and anorgasmia [10].

Depression can diminish sexual desire and the ability to experience sexual pleasure, due to negative thoughts, low self-esteem and feelings of hopelessness. In addition, the fatigue and apathy associated with depression can make sexual activity feel burdensome [10].

A recent systematic review and meta-analysis by Goncalves et al (2023) reviewed 12-cross sectional studies of participants diagnosed with Major Depression Disorder (MDD) not on pharmacological treatment [11].

Table 4 outlines the results from the review. The main finding was that sexual dysfunction is common in untreated depression. Other findings were that women with depression generally report higher rates of sexual dysfunction than men. Sexual desire appears to be the most affected aspect of sexual function [11].

Limitations of the study noted were sample size and considerable variation between studies in diagnostic criteria and measure for sexual function [11].

Table 4: Sexual dysfunction reported in women and men with MDD and not on pharmacological treatment (adapted from Goncalves et al, 2023)

Type of sexual dysfunction	Women	Men
Reduced sexual desire	65.30% (95% CI 45:86 – 84.73)	40.32% (95% CI: 22.19 – 58.46)
Arousal problems	47.22% (95% CI: 34.86 – 59.58)	26.45% (95% CI: 12.26 – 40.63)
Orgasm difficulties	34.17% (95% CI 18.87 – 50.46)	35.27% (95% CI: 5.13 – 65.41)
Reduce sexual satisfaction	33.91% (95% CI 17.48 – 50.34)	23.05% (95% CI: 13.60 – 32.51)
Lubrication difficulties	36.98% (95% CI 28.42 – 45.54)	-
Erectile problems	-	32.07% (95% CI: 26.14 – 37.99)
Overall sexual dysfunction	82.75% (95% CI: 74.71 –9 0.78)	63.26% (95% CI: 52.83 – 73.69)

Source: Adapted from Gonçalves, W.S., Gherman, B.R., Abdo, C.H.N. *et al.* Prevalence of sexual dysfunction in depressive and persistent depressive disorders: a systematic review and meta-analysis. *Int J Impot Res* **35**, 340–349 (2023). https://doi.org/10.1038/s41443-022-00539-7 (accessed 10 August 2026)

2.2.2.2 Anxiety disorders

Anxiety disorders including generalised anxiety disorder (GAD), social anxiety disorder (SAD) and panic disorder can lead to sexual dysfunction [10].

For example, anxiety may present as performance anxiety, leading to erectile dysfunction or premature ejaculation in males and arousal difficulties in females. Anticipation of anxiety during sexual encounters can hinder sexual arousal, contributing to sexual dissatisfaction or lead to avoidance of sexual activity [10].

Anxiety triggers the release of stress hormones such as cortisone and adrenaline. The fight or flight state caused by anxiety may interfere with sexual desire [10].

Herder et al (2023) systemic review evaluated the prevalence of sexual functioning in psychotropic-free psychiatric patients without known somatic disease or substance use. The prevalence of overall sexual dysfunction for anxiety disorders (from 3 studies) was between 33% - 75%. The most affected sexual domain affected was found to be orgasmic dysfunction [12].

Table 5 provides a summary of the types of sexual dysfunction reported in the studies in patients with anxiety disorders reviewed.

Table 5: Prevalence of types of sexual dysfunction reported in psychotropic-free patients with anxiety disorders adapted from Herder et al (2023)

Studies in patients with anxiety	General	Sexual desire	Arousal difficulties	Orgasm difficulties	Reduced satisfaction
Figueira et al (2001) *(panic disorder)*	75% sexual dysfunction	Males: 14% hypoactive sexual desire disorder	Males: 7% erectile dysfunction	Males: 21% premature ejaculation	
Figueira et al (2001) *(social phobia)*	33% sexual dysfunction	Females: 21% hypoactive sexual desire disorder	-	Males: 48% premature ejaculation, 5% orgasmic disorder Women: 18% orgasmic disorder	-
Bodinger et al et al (2002)		Less frequency of sexual thoughts, desire and more loss of desire during intercourse	Males: less arousal Females: less lubrication/arousal	Males: 33% premature ejaculation, less frequency of orgasm	Males: less satisfaction Females: less satisfaction
Kendurkar et al (2008)	64% reported sexual dysfunction (OR 2.0)	Low desire most prevalence for both genders	Men: 24% erectile dysfunction	Females: 44% orgasmic dysfunction	-

Source: Adapted from Herder, T., Spoelstra, S. K., Peters, A. W. M., & Knegtering, H. (2023). Sexual dysfunction related to psychiatric disorders: A systematic review. *Journal of Sexual Medicine, 20*(7), 965–976. https://doi.org/10.1093/jsxmed/qdad074 (accessed 10 August 2026).

2.2.3 Other factors

2.2.3.1 Co-morbid conditions relating to a psychiatric diagnosis

Multiple medical illnesses affect sexual functioning. A review by Leemans et al (2025) highlighted the presence of sexual dysfunction and symptoms experienced in different chronic conditions [13].

Co-morbidities such as cardiovascular disease, diabetes mellitus and obesity are often prevalent in people with mental health conditions [14].

Table 6 below provides a summary of sexual problems related to several chronic conditions.

Table 6: Examples of symptoms of sexual dysfunction in certain medical illnesses (Leemans et al 2025)

Comorbidity category	Examples of symptoms of sexual dysfunction
Cardiovascular disease	Erectile dysfunction, reduced sexual desire, reduced sexual satisfaction
Diabetes mellitus	Erectile dysfunction, decreased libido, orgasmic dysfunction, arousal difficulties
Obesity/metabolic syndrome	Reduces libido, erectile dysfunction, reduced arousal, reduced sexual satisfaction
Neurological disorders	Impaired arousal, erectile dysfunction, orgasmic dysfunction, reduced desire

Source: Adapted from Leemans C, Van den Broucke S, Jeitani C. Sexual Dysfunction in Patients with Chronic Non-Genital Physical Disease: An Umbrella Review. *International Journal of Environmental Research and Public Health*. 2025;22(2):157. PMID: 40003383. (accessed 4 August 2026).

2.2.3.2 Medicine-induced sexual side effects

Sexual side effects are well-recognised with serotonergic antidepressants, particularly SSRIs (fluoxetine, sertraline, paroxetine, citalopram, escitalopram) and SNRIs (venlafaxine). These medicines are used in the treatment of mental health conditions, such as depression and anxiety [15,16].

It has been suggested that up to 80% of patients taking SSRIs experience sexual side effects [15].

Reported side effects include decreased libido, impaired sexual arousal, erectile dysfunction, delayed ejaculation, delayed orgasm, and anorgasmia. Long-lasting sexual side effects occurring or continuing after treatment discontinuation have been reported. These symptoms are grouped into the syndrome PSSD [16,17].

<u>Possible mechanisms</u>

SSRIs inhibit the serotonin transporter (SERT) on presynaptic neurons. This reduces reuptake of serotonin (5-HT) into the presynaptic terminal and increases serotonin connections within the synaptic cleft. Over time, adaptive changes occur in serotonergic receptors and downstream neurotransmitter systems, contributing to antidepressant efficacy (16,17).

Sexual dysfunction associated with SSRIs is thought to be primarily from enhanced serotonergic neurotransmission. Each SSRI has unique pharmacodynamic and pharmacokinetic properties. Downstream biological effects may vary between different medicines (16, 17).

Table 7 below outlines possible biological pathways proposed in the development of sexual side effects with SSRIs (16,17).

Table 7: Possible biological pathways sexual side effects of SSRIs and related symptoms

Effects due to increased serotonin	Examples of possible side effects
Increased 5-HT2A and 5-HT2C receptor stimulation	Suppressed sexual desire, impaired orgasmic function
Dopamine inhibition	Reduced libido and impaired sexual response
Nitrous oxide synthase activity inhibition	Erectile dysfunction, arousal difficulties
Spinal reflex pathway inhibition	Delayed ejaculation, anorgasmia

Source: Adapted from:

- Zini J, Turecki G. Antidepressant-Induced Sexual Dysfunction in Adults: A Targeted Scoping Review and Clinical Update. J Clin Psychopharmacol. 2026 Jun 24. doi: 10.1097/JCP.0000000000002210. Epub ahead of print. PMID: 42333401. (accessed 6 August 2026).
- Edinoff AN, Akuly HA, Hanna TA, et al. Selective Serotonin Reuptake Inhibitors and Adverse Effects: A Narrative Review. *Neurology International*. 2021;13(3):387-401. doi:10.3390/neurolint13030038 (accessed 6 August 2026).

Comments

Symptoms of sexual dysfunction are common among individuals with psychiatric disorders, including depression and anxiety.

Factors such as age, co-existing psychiatric disorders and other medical conditions or medicines may influence risks of sexual problems as they are independently associated with sexual dysfunction themselves

Sexual side effects may be a class effect for SSRIs and SNRIs, due to increased serotonergic neurotransmission. However, the presentation, frequency, severity and patterns of sexual side effects may differ between different SSRIs and SNRIs due to differences in pharmacodynamic and pharmacokinetic properties and, in addition to potential influential factors within an individual patient.

Interestingly, a recent study by Ketilsdottir et al (2026) found that high serotonergic activity before treatment with an SSRI may increase the risk for SSRI-induced sexual side effects, predominantly orgasm dysfunction. This study used Loudness dependence of auditory evoked potentials (LDAEP), a form of event-related potentials measured by electroencephalograms (EEG), that is thought to be inversely related to central serotonin activity. The findings are preliminary and further validation is needed.

In relation to diagnosis of a substance/medication-induced sexual dysfunction, the DSM-5-TR criteria includes prominent disturbance in sexual functioning, evidence that the symptoms occurred during/soon/after withdrawal, disturbance causes clinically significant distress and that the symptoms are no better explained by a non-substance/medicine-induced sexual dysfunction or another disorder.

This formal diagnosis of medicine-induced sexual dysfunction is interesting noting that the medicine may cause side effects that contribute to the symptoms of sexual dysfunction, however, may not meet the criteria for the diagnosis depending on the individuals' experiences plus the presence of any other possible factors that can also cause symptoms of sexual dysfunctions.

3 Prescribing information

This section reviews the sexual side effects of SSRIs and venlafaxine listed in the New Zealand data sheets (the data sheet) and overseas prescribing information.

A review of sexual related MedDRA terms was undertaken to understand the different symptoms of sexual dysfunction that can occur, including those specific to males and females. These terms were then compared to those listed currently listed in SSRI and venlafaxine prescribing information.

3.1.1 MedDRA [18]

MedDRA is a standardised medical terminology to facilitate sharing of regulatory information about medicines between countries and organisations.

Figure 1 below outlines the hierarchy of MedDRA terms. There are 5 levels to the MedDRA hierarchy, arranged from very specific to very general.

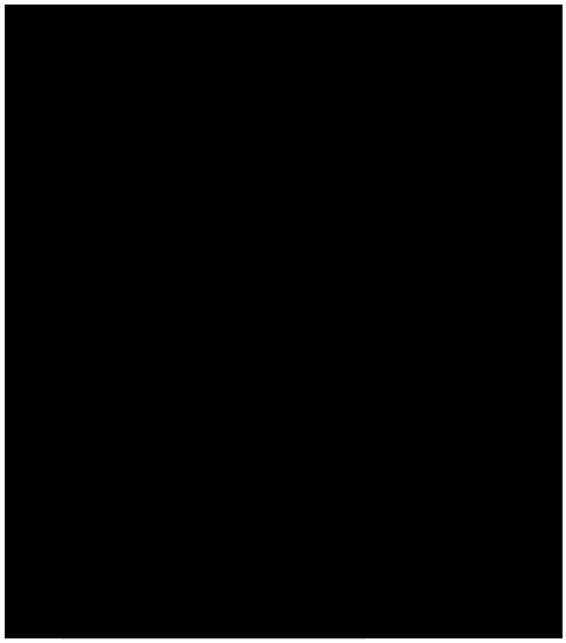
At the most specific level is the 'lowest level term' (LLTs). The LLTs reflect how an observation might be reported in practice.

The next level is the 'Preferred Term' (PTs). This is a distinct descriptor (single medial concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure and medical, social or family history characteristic. Each LLT is linked to only one PT. Each PT has a least one LLT (itself) as well as synonyms and variants.

Related PTs are grouped together into 'High Level Terms' (HLTs) based upon anatomy, pathology, physiology, aetiology or function. HLTs related to each other by anatomy, pathology, physiology, aetiology or function are linked to 'High Level Group Terms' (HLGTs).

HLGTs are grouped into 'System Organ Classes' (SOCs) which are groupings by aetiology, manifestation site or purpose.

Figure 1: Example of hierarchy of MedDRA terms



Source: Medical Dictionary for Regulatory Activities (MedDRA). (n.d.). MedDRA. International Council for Harmonisation (ICH). URL: www.meddra.org/ (accessed 20 July 2026).

Adverse reactions of medicines are listed in prescribing information using MedDRA terms, most commonly the PT.

A PT may be represented in more than one SOC. This characteristic is called 'multiaxiality'. For data collection, the primary SOC allocation is chosen. An example of this is provided in Figure 2 below.

Figure 2: Example of multiaxiality of MedDRA terms



Source: Medical Dictionary for Regulatory Activities (MedDRA). (n.d.). MedDRA. International Council for Harmonisation (ICH). URL: www.meddra.org/ (accessed 20 July 2026).

The New Zealand Data Sheet Template Explanatory Guide provides guidance for sponsors about data sheet requirements.

Generally, a list of adverse reactions included in section 4.8 is required, presented according to the MedDRA SOC. MedDRA terms should be classified according to the most relevant SOC related to the target organ.

Adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology. This will usually be the PT level, although there may be instances where the LLT or HLT may be used.

3.1.2 Sexual dysfunction related MedDRA terms [19]

In MedDRA, symptoms of sexual problems are predominantly included under the SOC 'Psychiatric disorders' and the SOC 'Reproductive system and breast disorders'.

Table 8 (a) and (b) outlines the hierarchy of terms in SOC 'Psychiatric disorders' and SOC 'Reproductive system and breast disorders' related to sexual problems. Note that the most relevant PTs have been included only. MedDRA version 29.1 is used.

Some PTs are represented in both SOCs. In this circumstance, the primary SOC as classified by MedDRA has been used to categorise these terms.

Table 8 (a): Sexual related side effects and types of sexual dysfunction MedDRA terms within SOC 'Psychiatry disorders', by hierarchy

SOC: Psychiatric disorders			
HLGT: Sexual dysfunctions, disturbances and gender identity disorders			
HLT: Orgasmic disorders and disturbances	*HLT: Sexual arousal disorders*	*HLT: Sexual desire disorders*	*HLT: Sexual dysfunction NEC*
PT Anorgasmia LLT Anorgasmia LLT Inability to orgasm PT Female orgasmic disorder LLT Abnormal orgasm (female) LLT Female orgasmic disorder LLT Inhibited female orgasm LLT Psychosexual dysfunction with inhibited female orgasm PT Male orgasmic disorder LLT Abnormal orgasm (male) LLT Inhibited male orgasm LLT Male orgasmic disorder LLT Psychosexual dysfunction with inhibited male orgasm PT Orgasm abnormal LLT Delayed orgasm LLT Orgasm abnormal LLT Painful orgasm LLT Premature orgasm PT Orgasmic sensation decreased LLT Orgasmic sensation decreased PT Premature ejaculation LLT Ejaculation premature LLT Premature ejaculation LLT Premature ejaculation disorder LLT Prospermia LLT Psychosexual dysfunction with premature ejaculation PT Spontaneous orgasm LLT Spontaneous orgasm	PT Disturbance in sexual arousal LLT Disturbance in arousal NOS LLT Disturbance in sexual arousal LLT Increased sexual arousal LLT Sexual arousal decreased PT Psychogenic erectile dysfunction LLT Psychogenic erectile dysfunction LLT Psychogenic impotence PT Sexual inhibition LLT Sex inhibition LLT Sexual inhibition PT Inadequate lubrication LLT Inadequate lubrication	PT Compulsive sexual behaviour LLT Compulsive sexual behavior LLT Compulsive sexual behaviour PT Excessive masturbation LLT Excessive masturbation PT Excessive sexual fantasies LLT Excessive sexual fantasies PT Hypersexuality LLT Hypersexuality LLT Nymphomania LLT Satyrism PT Kluver-Bucy syndrome LLT Kluver-Bucy syndrome PT Libido decreased LLT Female hypoactive sexual desire disorder due to a general medical condition LLT Hypoactive sexual desire disorder LLT Hyposexuality LLT Libido decreased LLT Male hypoactive sexual desire disorder due to a general medical condition LLT Sexual desire decreased LLT Sexual feeling decreased PT Libido disorder LLT Influence on libido LLT Libido disorder LLT Libido disorder NOS LLT Sexual desire disorder PT Libido increased LLT Increased libido LLT Libido increased LLT Sexual desire increased PT Loss of libido LLT Lack of libido LLT Libido lack LLT Libido loss of LLT Loss of libido PT Sexual aversion disorder LLT Sexual aversion disorder	PT Dyspareunia LLT Coitus painful LLT Deep dyspareunia LLT Dyspareunia LLT Dyspareunia (female excl psychogenic) LLT Dyspareunia (male excl psychogenic) LLT Dyspareunia NOS LLT Dyspareunia psychogenic LLT Female dyspareunia due to a general medical condition LLT Male dyspareunia due to a general medical condition LLT Painful intercourse LLT Post coital pain LLT Psychogenic dyspareunia LLT Psychosexual dysfunction with functional dyspareunia LLT Superficial dyspareunia LLT Vaginismus (excl psychogenic) PT Genito-pelvic pain/penetration disorder LLT Colpospasm LLT Genito-pelvic pain/penetration disorder LLT Psychogenic vaginismus LLT Vaginal spasm LLT Vaginismus LLT Vaginismus psychogenic

Table 8 (b): Sexual related side effects and types of sexual dysfunction MedDRA terms within SOC 'Reproductive system and breast disorders', by hierarchy

SOC: Reproductive system and breast disorders

HLGT: Sexual function and fertility disorders

HLT: Erection and ejaculation conditions and disorders

- PT Ejaculation delayed
  - LLT Ejaculation delayed
  - LLT Ejaculation inhibited
- PT Ejaculation disorder
  - LLT Abnormal ejaculation
  - LLT Dribbling ejaculation
  - LLT Ejaculation abnormal
  - LLT Ejaculation disorder
  - LLT Ejaculation disorder NOS
  - LLT Weak ejaculation
- PT Ejaculation failure
  - LLT Anejaculation
  - LLT Ejaculation decreased
  - LLT Ejaculation failure
- PT Retrograde ejaculation
  - LLT Retrograde ejaculation
- PT Spontaneous ejaculation
  - LLT Spontaneous ejaculation
- PT Spontaneous penile erection
  - LLT Erection nocturnal
  - LLT Prolonged morning erection
  - LLT Spontaneous penile erection
- PT Erectile dysfunction
  - LLT Decreased frequency of erections
  - LLT Erectile disturbance
  - LLT Erectile dysfunction
  - LLT Erectile dysfunction NOS
  - LLT Erection decreased
  - LLT Erection failure
  - LLT Erection inadequate
  - LLT Frigidity and impotence
  - LLT Impotence
  - LLT Impotence aggravated
  - LLT Impotent
  - LLT Impotentia erigendi
  - LLT Inability to maintain erection
  - LLT Male erectile disorder
  - LLT Male erectile disturbance due to general medical condition
  - LLT Potency disturbance
- PT Priapism
  - LLT High-flow priapism
  - LLT Ischaemic priapism
  - LLT Ischemic priapism
  - LLT Low-flow priapism
  - LLT Non-ischaemic priapism
  - LLT Non-ischemic priapism
  - LLT Priapism
  - LLT Priapism aggravated
- PT Erection increased
  - LLT Erection increased
  - LLT Erection increased (exc priapism)
  - LLT Erection increased (excl priapism)
  - LLT Erection prolonged
  - LLT Potency of penis erection increased
- PT Leriche syndrome
  - LLT Aortoiliac occlusive disease
  - LLT Leriche syndrome
- PT Nocturnal emission
  - LLT Nocturnal emission
- PT Organic erectile dysfunction
  - LLT Impotence of organic origin
  - LLT Lack of early morning erection
  - LLT Organic erectile dysfunction
  - LLT Organic impotence
- PT Painful ejaculation
  - LLT Painful ejaculation
- PT Painful erection
  - LLT Painful erection

HLT: Sexual function and fertility disorders NEC

- PT Male sexual dysfunction
  - LLT Male sexual dysfunction
  - LLT Male sexual dysfunction NEC
- PT Female sexual dysfunction
  - LLT Female sexual dysfunction
  - LLT Female sexual dysfunction NEC
- PT Female sexual arousal disorder
  - LLT Female sexual arousal disorder
  - LLT Frigidity
- PT Sexual dysfunction
  - LLT Decreased genital sensation
  - LLT Post-SSRI sexual dysfunction
  - LLT Sexual disorder NOS
  - LLT Sexual dysfunction
  - LLT Sexual dysfunction NOS
  - LLT Sexual function abnormal
  - LLT Sexual function decreased
  - LLT Sexual problem
- PT Persistent genital arousal disorder
  - LLT Persistent genital arousal disorder
  - LLT Restless genital syndrome

HLGT: Vulvovaginal disorders (excluding infections and inflammations)

HLT: Vulvovaginal signs and symptoms

- PT Vulvovaginal dryness
  - LLT Dryness vaginal
  - LLT Vaginal dryness
  - LLT Vulvovaginal dryness

HLGT: Reproductive tract disorders NEC			
HLT: Reproductive tract disorders NEC (excluding neoplasms)			
PT Genital anaesthesia LLT Genital anaesthesia LLT Genital anesthesia PT Genital hypoaesthesia LLT Genital hypoaesthesia LLT Genital hypoesthesia LLT Hypoaesthesia of genital male LLT Hypoaesthesia of penis LLT Hypoesthesia of genital male LLT Hypoesthesia of penis LLT Penile numbness LLT Perineal numbness LLT Scrotal hypoaesthesia LLT Scrotal hypoesthesia LLT Vulvovaginal hypoaesthesia LLT Vulvovaginal hypoesthesia	PT Genital paraesthesia LLT Genital paraesthesia LLT Genital paresthesia LLT Paraesthesia of genital female LLT Paraesthesia of genital male LLT Paraesthesia of penis LLT Paresthesia of genital female LLT Paresthesia of genital male LLT Paresthesia of penis LLT Penile tingling LLT Scrotal paraesthesia LLT Scrotal paresthesia		

A range of sexual side effects, types of sexual dysfunction terms and the terms 'sexual dysfunction and 'male/female sexual dysfunction' are noted within the MedDRA terminology. These terms can be used in prescribing information to describe adverse reactions.

Several PTs are included in both SOC 'reproductive system and breast disorders' and 'psychiatric disorders, these PTs are listed below:

- *Primary SOC 'psychiatry disorders'*, secondary SOC 'reproductive system and breast disorder'
  - PT 'painful ejaculation'
  - PT 'premature ejaculation'
  - PT 'psychogenic erectile dysfunction'
  - PT 'libido decreased'
  - PT 'libido disorder'
  - PT 'libido increased'
  - PT 'male orgasmic disorder'
  - PT 'female orgasmic disorder'
  - PT 'orgasm abnormal'
  - PT 'orgasmic sensation decreased'
  - PT 'spontaneous orgasm'

- *Primary SOC 'reproductive system and breast disorders',* secondary SOC 'psychiatry disorders'
  - PT 'erectile dysfunction'
  - PT 'erection increased'
  - PT 'organic erectile dysfunction'
  - PT 'female sexual dysfunction'
  - PT 'male sexual dysfunction'
  - PT 'painful ejaculation'
  - PT 'sexual dysfunction'
  - PT 'female sexual arousal disorder'

The primary SOC for PT terms 'sexual dysfunction', 'male sexual dysfunction' and 'female sexual dysfunction' is SOC 'reproductive system and breast disorders'.

3.2 Sexual side effects

Current symptoms of sexual dysfunction and sexual side effects that are listed in section 4.8 and section 4.4 of New Zealand and overseas prescribing information for SSRIs and SNRIs are compared below for each medicine.

The following searches were used to find the prescribing information:

- NZ: Data Sheets and Consumer Medicine Information
- Australia: TGA eBusiness Services
- UK: MHRA Products | Home
- US: DailyMed

3.2.1 Section 4.8

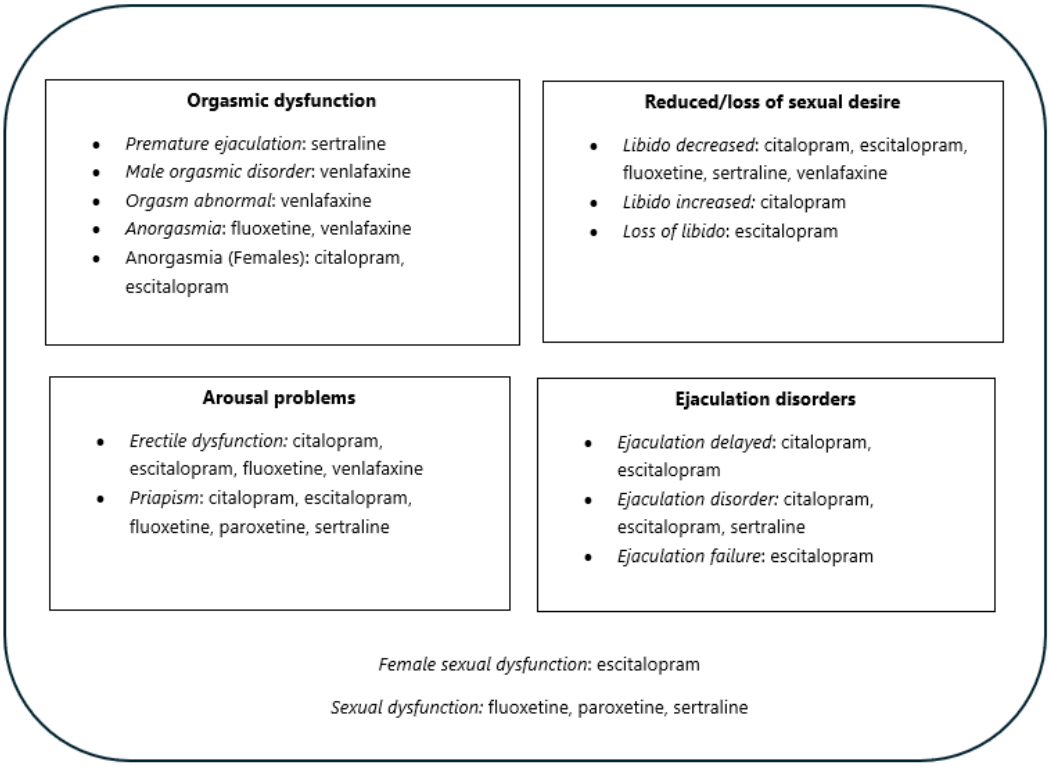
In the adverse reporting section of prescribing information, side effects may be reported from clinical trials and/or post marketing.

The frequency of an adverse event may differ depending on the denominator used for calculation. Therefore, the frequencies have not been included as the presentation of adverse effect data between different prescribing information and between medicine products are variable.

3.2.1.1 Summary of current sexual side effects listed in section 4.8 of the data sheets

A summary of the current sexual side effects listed in section 4.8 of SSRI and venlafaxine data sheets are outlined in Figure 3, categorised by sexual domain.

Figure 3: Sexual side effects listed in section 4.8 of SSRIs and venlafaxine, as per each medicine data sheet, categorised by sexual domain



Source: Medsafe. 2026. *Product Application Search*. 7 July 2026. URL: www.medsafe.govt.nz/DbSearch/ (accessed 20 July 2026)

Comments

This overview shows the current variability in sexual side effects listed in section 4.8 of the data sheets of SSRIs and SNRIs.

The PT 'sexual dysfunction' is listed in the fluoxetine, paroxetine and sertraline data sheet and the escitalopram data sheet lists 'female sexual dysfunction'. These side effects do not fit into a specific sexual function domain problem.

The PT 'sexual dysfunction' and PT 'female sexual dysfunction' may be used as a broad category to describe problems with sexual function that don't fit a more specific diagnosis or when insufficient detail is available.

When these PT are used, it may mean that a sexual problem may occur, but symptoms are not further specified. This is contrast to other terms such as PT 'erectile dysfunction' or PT 'anorgasmia' which are used to describe more specific types of sexual dysfunction symptoms/problems.

Priapism is not typically grouped under 'sexual dysfunction' in the same way as erectile dysfunction, as it is often considered a distinct sexual adverse reaction affecting penile erection rather that impaired sexual function. However, as this ADR is listed in MedDRA under the search terms plus is listed in the data sheets, it has been included in this report

3.2.1.2 Citalopram

Table 9 shows the sexual side effects listed in citalopram data sheet in comparison with international citalopram prescribing information.

Table 9: Sexual side effects of citalopram in NZ, Australia, UK and US prescribing information

NZ Celapram (26 Nov 2025)	**Australia** Celapram (26 Sept 2025)	**UK** Cipramil (10 Nov 2023)	**US** Citalopram (Aug 2023)
Male specific			
Ejaculation disorders (primarily ejaculatory delay)	Ejaculation disorders (primarily ejaculatory delay)	Ejaculation disorder	Ejaculation disorder (primarily ejaculatory delay)
Impotence	Impotence	Impotence	Impotence
Priapism	Priapism	Priapism	Priapism
-	-	Ejaculation failure	-
Female specific			
Anorgasmia	Anorgasmia	-	Anorgasmia
-	Abnormal orgasm	Abnormal orgasm	-
Male and female / not specified			
Libido decreased	Libido decreased	Libido decreased	Libido decreased
Increased libido	Increased libido	Libido increased	Increased libido

Comments

Additional adverse effects listed in other citalopram prescribing information compared to the data sheet are 'Abnormal orgasm (female)' (Australia and UK) and 'ejaculation failure' (UK).

3.2.1.3 Escitalopram

Table 10 shows the sexual side effects listed in the escitalopram data sheet in comparison international escitalopram prescribing information.

Table 10: Sexual side effects of escitalopram in NZ, Australia, UK and US prescribing information

NZ Lexapro (8 Aug 2024)	**Australia** Escitalopram Sandoz (26 Feb 2025)	**UK** Cipralex (21 Jan 2026)	**US** Escitalopram (May 2023)
Male specific			
Impotence	Impotence	Impotence	Importance
Ejaculation disorder	Ejaculation disorder	Ejaculation disorder	Ejaculation disorder
Ejaculation failure	Ejaculation failure	-	-
Ejaculation delayed	Ejaculation delayed	-	Ejaculatory delay
Priapism	Priapism	Priapism	Priapism
Female specific			
Anorgasmia	Anorgasmia	Anorgasmia	Anorgasmia
Sexual function abnormality	Sexual function abnormality	-	-
Male and female / not specified			
Libido decreased	Libido decreased	Libido decreased	Libido decreased
Loss of libido	Loss of libido	-	-

Comments

No additional side effects are noted in other escitalopram prescribing information compared to NZ.

3.2.1.4 Fluoxetine

Table 11 shows the sexual side effects listed in fluoxetine data sheet in comparison with international fluoxetine prescribing information.

Table 11: Sexual side effects of fluoxetine in NZ, Australia, UK and US prescribing information

NZ Arrow Fluoxetine (9 July 2024)	Australia Fluoxetine Sandoz (25 Sept 2024)	UK Fluoxetine (6 May 2026)	US Prozac (August 2023)
Male specific			
Abnormal ejaculation	Abnormal ejaculation	-	Abnormal ejaculation
Impotence	Impotence	Erectile dysfunction	Impotence
Priapism	Priapism	-	Priapism
-	-	Ejaculation disorder (includes ejaculation failure, ejaculation dysfunction, premature ejaculation, ejaculation delayed, retrograde ejaculation)	-
Female specific			
-	-	-	Orgasmic dysfunction
-	-	-	Anorgasmia
Male and female / not specified			
Libido decreased	Libido decreased	Libido decreased	Libido decreased
Anorgasmia	Anorgasmia	Anorgasmia	-
Sexual dysfunction (occasionally persisting after treatment discontinuation)	Sexual dysfunction (occasional persistence after treatment discontinuation)	Sexual dysfunction (includes asthenia)	Sexual dysfunction (occasionally persist after discontinuation of treatment)
-	-	Loss of libido	-
-	-	Orgasm abnormal	-

Comments

Additional adverse effects listed in other fluoxetine prescribing information compared to the data sheet include:

- UK SmPC: 'ejaculation disorder (includes ejaculation failure, ejaculation dysfunction, premature ejaculation, ejaculation delayed, retrograde ejaculation), 'loss of libido', 'orgasm abnormal'.
- US label: 'orgasmic dysfunction (females)' and 'anorgasmia (females)'.

3.2.1.5 Paroxetine

Table 12 shows the sexual side effects listed in paroxetine data sheet in comparison with international paroxetine prescribing information.

Table 12: Sexual side effects of paroxetine in NZ, Australia, UK and US prescribing information

NZ **Aropax** (3 Jan 2025)	Australia Aropax (7 Jan 2026)	UK Paroxetine (Clydesdale Pharma Ltd) (8 Oct 2025)	US Paroxetine (Sept 2023)
Male specific			
Priapism	-	Priapism	-
-	Impotence	-	-
-	Abnormal ejaculation	-	-
Female specific			
-	-	-	-
Male and female / not specified			
Sexual dysfunction	Sexual dysfunction	Sexual dysfunction	-
	Libido decreased		-

Comment

Additional adverse effects listed in other paroxetine prescribing information compared to the data sheet include 'impotence', 'abnormal ejaculation' and 'libido decreased' (Australia). These ADRs are listed as observed in clinical trials and that the causality has not necessarily been established.

3.2.1.6 Sertraline

Table 13 shows the sexual side effects listed in sertraline data sheet in comparison with international paroxetine prescribing information.

Table 13: Sexual side effects of sertraline in NZ, Australia, UK and US prescribing information

NZ (Setrona, 11 Feb 2025)	Australia (Zoloft, 30 June 2026)	UK (Sertraline (Bristol Laboratories Limited), 1 Oct 2025)	US (Sertraline (Amneal Pharmaceuticals), Jan 2026)
Male specific			
Ejaculation disorder	Ejaculation disorder	-	-
Premature ejaculation	-	Premature ejaculation	-
Priapism	Priapism	Priapism	Priapism
-	-	Ejaculation failure	Ejaculation failure
-	-	Erectile dysfunction	Erectile dysfunction
-	-	-	Male sexual dysfunction
Female specific			
-	-	Female sexual dysfunction	-
-	-	-	-
Male and female / not specified			
Libido decreased	Libido decreased	Libido decreased	Libido decreased
Sexual dysfunction	Sexual dysfunction	Sexual dysfunction	-

Comments

Additional adverse effects listed in other sertraline prescribing information compared to the data sheet include 'ejaculation failure' and 'erectile dysfunction' (UK and US).

The US label specifically includes 'male sexual dysfunction' and the UK SmPC includes both 'female sexual dysfunction' and 'sexual dysfunction'.

3.2.1.7 Venlafaxine

Table 14 shows the sexual side effects listed in venlafaxine data sheet in comparison with and international paroxetine prescribing information.

Table 14: Sexual side effects of venlafaxine NZ, Australia, UK and US prescribing information

NZ (Efexor – XR, 11 June 2024)	**Australia** (Efexor-XR, 2 Feb 2026)	**UK** (Efexor -XL, 15 May 2024)	**US** (Venlafaxine hydrochloride ER (Advagen Pharma Ltd), Aug 2023)
Male specific			
Erectile dysfunction	Erectile dysfunction	Erectile dysfunction	-
Ejaculation disorder	Ejaculation disorder	-	-
-	Abnormal ejaculation (mostly delayed ejaculation)	-	-
-	Impotence	-	Impotence
-	-	-	Abnormal ejaculation/orgasm
-	-	Erectile disorder	-
Female specific			
-	Orgasmic dysfunction (mostly delayed orgasm, abnormal orgasm, anorgasmia)	-	-
Male and female / not specified			
Libido decreased	Libido decreased	Libido decreased	Libido decreased
Anorgasmia	Anorgasmia	Anorgasmia	-
Abnormal orgasm	Abnormal orgasm	Abnormal orgasm	-

Comments

Additional adverse effects listed in other venlafaxine prescribing information compared to the data sheet include 'abnormal ejaculation' (Australia and US), 'erectile disorder' (UK) and 'orgasmic dysfunction (females) (mostly delayed orgasm, abnormal orgasm, anorgasmia)' (Australia).

3.2.2 Summary of section 4.8

A further comparison between each SSRI and venlafaxine sexual side effects listed in adverse effects sections of the NZ, Australian, UK and US prescribing information was undertaken.

The adverse effects listed are mapped to the corresponding sexual symptoms MedDRA PTs and split into male specific, female specific and male/female/not specified categories.

3.2.2.1 Male specific sexual side effects in SSRI/SNRI prescribing information

Table 15 shows the male specific sexual side effects listed in adverse effects section of SSRI and venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA Preferred Term (PT).

Table 15: Summary of male specific sexual side effects listed in adverse effects section of SSRI, venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA Preferred Term (PT)

	Citalopram	Escitalopram	Fluoxetine	Paroxetine	Sertraline	Venlafaxine
Male specific						
SOC 'Psychiatric disorders' – HLGT 'Sexual dysfunctions, disturbances and gender identity disorders'						
HLT 'Orgasmic disorders and disturbances'						
PT 'premature ejaculation'	✗	✗	✓	✗	✓	✗
PT 'male orgasmic disorder'	✗	✗	✗	✗	✗	✓[5]
HLT 'Sexual arousal disorders'						
PT 'psychogenic erectile dysfunction'	-	-	-	-	-	-
SOC 'Reproductive system and breast disorders' – HLGT 'Sexual function and fertility disorders'						
HLT: Erection and ejaculation conditions and disorders						
PT 'ejaculation delayed'	✓	✓	✓	✗	✗	✓
PT 'ejaculation disorder'	✓	✓	✓[2]	✓[3]	✓	✓[6]
PT 'ejaculation failure'	✓	✓	✓	✗	✓	✗
PT 'retrograde ejaculation'	✗	✗	✓	✗	✗	✗
PT 'spontaneous ejaculation'	-	-	-	-	-	-
PT 'spontaneous penile erection'	-	-	-	-	-	-
PT 'erectile dysfunction'	✓[1]	✓[1]	✓[1]	✓[4]	✓	✓[7]
PT 'priapism'	✓	✓	✓	✓	✓	✗
PT 'erection increased'	-	-	-	-	-	--
PT 'Leriche syndrome'	-	-	-	-	-	-
PT 'nocturnal emission'	-	-	-	-	-	-
PT 'organic erectile dysfunction'	-	-	-	-	-	-
PT 'painful ejaculation'	-	-	-	-	-	-
PT 'painful erection'	-	-	-	-	-	-
HLT: sexual function and fertility disorders NEC						
PT 'male sexual dysfunction'	✗	✗	✗	✗	✓	✗

Notes:

✓ = Listed in the data sheet.

✓ = Not listed in the data sheet, listed in at least one of Australian/UK and/or US prescribing information reviewed.

✗ = Not listed in the data sheet or the Australian, UK or US prescribing information reviewed,

1. Listed as LLT 'impotence' in data sheet.
2. Listed as LLT 'ejaculation abnormal' in data sheet.
3. Listed as LLT 'ejaculation abnormal' in Australian PI.
4. Listed as LLT 'impotence' in Australian PI.
5. Listed as LLT 'abnormal orgasm' in US label.
6. Listed as LLT 'abnormal ejaculation' in US label.
7. LLT 'erectile disorder' also listed in UK SmPC.

On review of the information in table 10, similarities and differences were identified between the medicines. These include:

Similarities

- Erection and ejaculation conditions and disorders are listed in most of the SSRIs and venlafaxine prescribing information.
- 'Ejaculation disorder' and 'erectile dysfunction' (often listed as the LLT 'impotence') are listed in all SSRIs/SNRIs.
- 'Priapism' is listed in all the SSRI prescribing information but not in venlafaxine prescribing information.
- 'Ejaculation delayed' is listed in the citalopram, escitalopram, fluoxetine and venlafaxine prescribing information.
- 'Ejaculation failure' is listed in the citalopram, escitalopram, fluoxetine and sertraline prescribing information.
- 'Premature ejaculation' is listed in the fluoxetine and sertraline prescribing information.

Differences

- The US venlafaxine label includes 'abnormal ejaculation/orgasm' which could be categorised under the MedDRA PT 'male orgasmic disorder'. No other venlafaxine or SSRI prescribing information list orgasm related disorders for males.
- The US sertraline prescribing information includes 'male sexual dysfunction'. This side effect was not found to be included in the Australian, UK or NZ prescribing information, nor for the other SSRIs/venlafaxine.

Comments

Overall, on the basis of what is currently listed in prescribing information, SSRIs and venlafaxine appear to mostly cause erection and ejaculation problems in males. This was generally seen across the medicines class.

Sexual side effects related to male orgasmic disorder was noted in the venlafaxine US label only. An association between effects on male orgasm with SSRIs/venlafaxine may be less certain. However, 'ejaculation delayed' could be considered related to a male orgasmic disorder.

On review of the data sheet information specifically as it is currently, fluoxetine and paroxetine have less male specific sexual related side effects listed compared to other SSRIs. If a class effect of specific types of sexual dysfunction is considered, data sheet updates may be necessary to list specific erection and ejaculatory related side effects.

3.2.2.2 Female specific sexual side effects in SSRI/SNRI prescribing information

Table 16 shows female specific sexual side effects listed in adverse effects section of SSRI and venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA Preferred Term (PT)

Table 16: Summary of female specific sexual side effects listed in adverse effects section of SSRI, venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA Preferred Term (PT)						
	Citalopram	**Escitalopram**	**Fluoxetine**	**Paroxetine**	**Sertraline**	**Venlafaxine**
Female specific						
SOC 'Psychiatric disorders' – HLGT 'Sexual dysfunctions, disturbances and gender identity disorders'						
HLT 'Orgasmic disorders and disturbances'						
PT 'anorgasmia'	✓	✓	✓	✗	✗	✓
PT 'female orgasmic disorder'	✓[1]	✗	✓	✗	✗	✓[3]
HLT 'Sexual arousal disorders'						
PT 'inadequate lubrication'	-	-	-	-	-	-
HLT: sexual dysfunction NEC						
PT 'genito-pelvic pain/penetration disorder'	-	-	-	-	-	-
SOC 'Reproductive system and breast disorders' – HLGT 'Sexual function and fertility disorders'						
HLT: sexual function and fertility disorders NEC						
PT 'female sexual dysfunction'	✗	✓[2]	✗	✗	✓	✗
PT 'female sexual arousal disorder'	-	-	-	-	-	-
SOC 'Reproductive system and breast disorders' – HLGT 'Vulvovaginal disorders (excluding infections and inflammation)						
HLT: Vulvovaginal signs and symptoms						
PT 'vulvovaginal dryness'	-	-	-	-	-	-

Notes:

✓ = Listed in the data sheet.

✓ = Not listed in the data sheet, listed in at least one of Australian/UK and/or US prescribing information reviewed.

✗ = Not listed in the data sheet or the Australian, UK or US prescribing information reviewed,

1. Listed as the LLT 'abnormal orgasm (females)' in Australian PI and UK SmPC
2. Listed as 'sexual function abnormality' in data sheet.
3. Includes female orgasmic dysfunction (mostly delayed orgasm, abnormal orgasm) in Australia PI.

Effects on female orgasm, specifically anorgasmia and/or orgasm abnormal were identified to be listed in most SSRI data sheets except for paroxetine and sertraline. Female orgasmic dysfunction is listed in the Efexor XR Australia PI.

'Female sexual dysfunction' is listed in the escitalopram data sheet and the UK sertraline SmPC.

Comments

Overall, there is a smaller number of sexual related side effects that are specifically listed for females in SSRI and venlafaxine prescribing information compared to male specific side effects.

On review of the data sheet information only, female specific sexual side effects are listed in the citalopram and escitalopram data sheets only. The risk of female specific sexual side effects relating to orgasm problems may be related to specific SSRIs, however, when reviewing other international prescribing information, similar side effects are also listed in fluoxetine and venlafaxine prescribing information.

No female specific side effects were noted to be listed in paroxetine prescribing information.

3.2.2.3 Male and female sexual side effects in SSRI/SNRI prescribing information

Table 17 outlines the male and female sexual side effects listed in adverse effects section of SSRI and venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA PT

Table 17: Summary of male and female sexual side effects listed in adverse effects section of SSRI, venlafaxine data sheets and UK/Aus/US prescribing information, categorised by MedDRA Preferred Term (PT)

	Citalopram	Escitalopram	Fluoxetine	Paroxetine	Sertraline	Venlafaxine
Male/female /not specified						
SOC 'Psychiatric disorders' – HLGT 'Sexual dysfunctions, disturbances and gender identity disorders'						
HLT 'Orgasmic disorders and disturbances'						
PT 'anorgasmia'	✗	✗	✓	✗	✗	✓
PT 'orgasm abnormal'	✗	✗	✓	✗	✗	✓
PT 'orgasmic sensation decreased'	-	-	-	-	-	-
PT 'spontaneous orgasm'	-	-	-	-	-	-
HLT 'Sexual arousal disorders'						
PT 'disturbances in sexual arousal'	-	-	-	-	-	-
PT 'sexual inhibition'	-	-	-	-	-	-
HLT 'sexual desire disorders'						
PT 'compulsive sexual behaviour'	-	-	-	-	-	-
PT 'excessive masturbation'	-	-	-	-	-	-
PT 'excessive sexual fantasies'	-	-	-	-	-	-
PT 'hypersexuality'	-	-	-	-	-	-
PT 'Kluver-Bucy syndrome'	-	-	-	-	-	-
PT 'libido decreased'	✓	✓	✓	✓	✓	✓
PT 'libido disorder'	-	-	-	-	-	-
PT 'libido increased'	✓	✗	✗	✗	✗	✗
PT 'loss of libido'	✗	✓	✓	✗	✗	✗
PT 'sexual aversion disorder'	-	-	-	-	-	-
HLT: sexual dysfunction NEC						
PT 'dyspareunia'	-	-	-	-	-	-
SOC 'Reproductive system and breast disorders' – HLGT 'Sexual function and fertility disorders'						
HLT: sexual function and fertility disorders NEC						
PT 'sexual dysfunction'	✗	✗	✓[1]	✓	✓	✗
SOC 'Reproductive system and breast disorders' – HLGT 'Reproductive tract disorders NEC'						
HLT: Reproductive tract disorders NEC (excluding neoplasms)						
PT 'genital anaesthesia'	-	-	-	-	-	-

PT 'genital hypoaesthesia'	-	-	-	-	-	-
PT 'genital paraesthesia'	-	-	-	-	-	-

Notes:

✓ = Listed in the data sheet.

✓ = Not listed in the data sheet, listed in at least one of Australian/UK and/or US prescribing information reviewed.

✗ = Not listed in the data sheet or the Australian, UK or US prescribing information reviewed,

1. Includes occasionally persisting after treatment discontinuation (note there is LLT 'Post-SSRI sexual dysfunction', under the PT 'sexual dysfunction'.

'Anorgasmia' and 'orgasm abnormal' is listed in prescribing information for fluoxetine and venlafaxine for both sexes only.

'Libido decreased' is listed in all the SSRI and venlafaxine prescribing information, in comparison to 'loss of libido' which was noted in only the escitalopram and fluoxetine prescribing information.

'Sexual dysfunction' is listed in the data sheets for fluoxetine, sertraline and paroxetine.

Comments

Libido decreased appears to be a listed sexual side effect in SSRIs and venlafaxine prescribing information.

Anorgasmia and orgasm abnormal relating to both genders is only listed in fluoxetine and venlafaxine disorders, whereas female specific anorgasmia is listed in other SSRIs prescribing information also.

The data sheet for fluoxetine is the only medicine to list that sexual dysfunction may persist after treatment discontinuation.

3.2.3 Section 4.4

In New Zealand, the data sheets for SSRIs and venlafaxine currently include a warning for sexual dysfunction in section 4.4. This warning is consistent with Australian and UK prescribing information (see below).

Sexual Dysfunction

SNRIs may cause symptoms of sexual dysfunction (see section 4.8). There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SNRIs.

It is noted that in US FDA labels, the warning relating to sexual dysfunction includes additional information. The warning is also seen with SNRIs. The following information is included in an escitalopram label.

Sexual Dysfunction

Use of SSRIs, including Escitalopram Capsules, may cause symptoms of sexual dysfunction [see Adverse Reactions (6.1)]. In male patients, SSRI use may result in ejaculatory delay or failure, decreased libido, and erectile dysfunction. In female patients, SSRI use may result in decreased libido and delayed or absent orgasm.

It is important for prescribers to inquire about sexual function prior to initiation of Escitalopram Capsules and to inquire specifically about changes in sexual function during treatment, because sexual function may not be spontaneously reported. When evaluating changes in sexual function, obtaining a detailed history (including timing of symptom onset) is important because sexual symptoms may have other causes, including the underlying psychiatric disorder. Discuss potential management strategies to support patients in making informed decisions about treatment.

Comments

The warning in SSRI and venlafaxine data sheets for sexual dysfunction does not list the types of sexual dysfunction symptoms that may be experienced, however, does reference to section 4.8 where specific symptoms are listed for each medicine.

The US label warning provides more information to prescribers such as sex specific side effects relating to the SSRI/SNRI class, and how sexual symptoms may have other causes including the underlying psychiatric disorder. It appears that in this warning the side effects listed are grouped as class effects and include ejaculatory delay or failure, decreased libido and erectile dysfunction for males and decreased libido and delayed or absent orgasm for females.

4 SCIENTIFIC INFORMATION

The literature was searched for articles about types of sexual dysfunction/sexual side effects with SSRIs/SNRIs, specifically relating to individual side effects as opposed to sexual dysfunction in general.

4.1.1 Sexual dysfunction associated with selective serotonin reuptake inhibitors in adults with depression: a systematic review and meta-analysis (Dagostin Ferraz et al, 2026) [20]

The aim of this publication was to evaluate the impact of SSRIs compared to placebo on sexual function in adults with depression through a systemic review and meta-analysis of randomised controlled trials (RCTs).

A systematic search was conducted using the terms 'sexual dysfunction', 'depression' and 'antidepressant' for RCTs up to June 2025.

A total of 13 RCTs were reviewed for qualitative synthesis and 6 of these were included for meta-analysis.

The 13 RCTs were published between 1990 and 2014, with study periods ranging from 1998 to 2013. The trials enrolled a total of 5,941 adult participants (aged 18 and over), including 2651 (44.6%) male and 3290 women (55.4%). All participants had a diagnosis of unipolar major depression. Studies included were conducted across multiple countries.

Mean age of participants across the studies ranged from 39.2 to 45.8 years. Baseline depression severity indicated moderate to severe depression for most participants.

Of the 5941 total participants, 2542 (42.8%) received SSRI treatment and the remainder were allocated to comparative groups including placebo.

Evaluation of sexual symptoms using the CSFQ scale

A total of 4 studies reported outcomes based on the Changes in Sexual Functioning Questionnaire (CSFQ). This is a 14-item self-reported, multiple-choice questionnaire designed to assess sexual functioning with total and domain scores derived from Likert-scale responses, where lower scores indicate greater sexual dysfunction.

Meta-analysis could only be performed for 2 studies. At the end of 8-weeks treatment with SSRIs compared to placebo, the mean difference in scores in men was -1.11. (95% CI -2.67 to 0.45, p=0.16, I^2 = 0%, 304 participants, 2 studies, moderate quality of evidence) and in females -1.68 (95% CI -4.28 to 0.93, p=0.23, I^2 = 75%, 467 participants, moderate quality of evidence). These results did not show a statistically significant difference between groups.

Evaluation of main side effects

Orgasm dysfunction (3 studies)

A total of 131 events were reported in the SSRI group versus 40 events in the placebo groups, corresponding to those that used SSRI had a 3.28 times higher risk of having orgasm dysfunction compared to controls (see Figure 4, certainty of evidence rated as high).

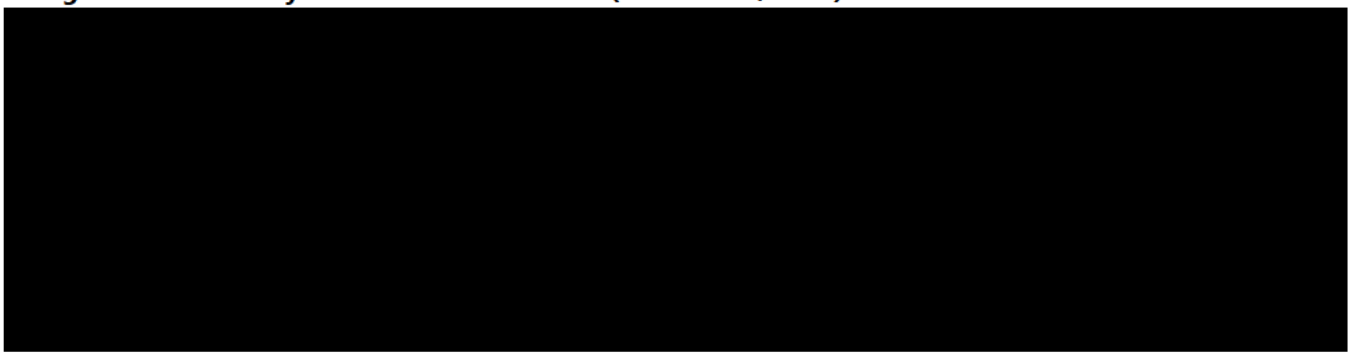
Figure 4: Meta-analysis of orgasm dysfunction (Ferraz et al, 2026)



Sexual satisfaction (3 studies)

Sexual satisfaction was reported by 60.8% of participants in the SSRI group (238/348) compared with 73.2% in the placebo group (291/398). These findings indicate that treatment with SSRI is associated with reduced sexual satisfaction compared to placebo. (Figure 5, moderate certainty of evidence).

Figure 5: Meta-analysis of sexual satisfaction (Ferraz et al, 2026)



Sexual desire (4 studies)

Meta-analysis showed a trend towards decreased sexual desire in SSRI users, however, the difference did not reach statistical significance (Figure 6, moderate certainty of evidence).

Figure 6: Sexual desire disorder (Ferraz et al, 2026)



<u>Discussion</u>

The authors conclude that the results of this study align with previous systematic reviews in that orgasmic dysfunction is the most prevalent sexual side effects of SSRIs. Sexual dissatisfaction is also previously reported as one of the domains most significantly affected by long-term SSRI use.

The effect on orgasmic function likely reflects serotonin's direct inhibitory effects on spinal ejaculatory reflexes and the neural circuits controlling orgasm. Increased serotonergic activity can suppress dopaminergic neurotransmission in key areas of the brain responsible for sexual motivation and arousal.

Comments

The results of the meta-analysis suggest that SSRI treatment versus placebo is associated with a statistically significant difference in orgasmic dysfunction (RR = 3.28) and reduced sexual satisfaction (RR = 1.21) in adults with moderate to severe major depression. A decreasing trend in sexual desire disorders was also identified however did not reach statistical significance.

A strength of this study is that it compared SSRI-treated patients with placebo in patients with depression. The results may suggest that for the side effects further analysed, the observed dysfunction may extend beyond the effects of the depression alone.

A limitation of this analysis is that males and females, plus different SSRIs were not grouped for analysis.

In addition, the authors also comment on the heterogeneity of sexual function assessment methods across studies limiting the ability to perform meta-analysis for all outcomes. Therefore only a small number of studies were used.

It was not clear what type of orgasmic dysfunction was reported in the studies. For example, this could include abnormal orgasms, anorgasmia and delayed ejaculation.

The relatively short follow up period in most studies (median 8 weeks) was noted. This period may not capture all sexual side effects, including those that may continue post discontinuation. In addition, to see any improvements in sexual function due to improvement in depression symptoms.

Sexual dysfunction may be underreported or inadequately assessed in some clinical trials. Furthermore, the studies included in the analysis were conducted between 1990 and 2014, and contemporary clinical trial practices may differ in their approach to sexual function assessment. It was noted that there were no recent RCTs included.

4.1.2 Antidepressant-induced sexual dysfunction in adults: a targeted scoping review and clinical update (Zini & Turecki, 2026) [16]

This was a scoping review relating to the prevalence, risk factors, mechanisms and management of antidepressant-induced sexual side effects in adults.

A search of PubMed was undertaken to identify studies between January 2000 and May 2025.

The information relevant to this report is summarised below.

Clinical presentation

Antidepressant induced sexual dysfunction (AISD) may affect multiple phases of the sexual response cycle, including desire (libido), arousal (erectile dysfunction, vaginal lubrication), orgasm (delayed ejaculation, anorgasmia) and genital sensation, affecting both sexes with differing prevalence and symptom severity.

Sexual side effects often emerge early during antidepressant treatment.

Diagnosis

Clinicians must distinguish between sexual symptoms attributable to underlying depression and those potentially related to treatment. Before treatment, up to 40% of men and 50% of women with depression report reduced libido. However, profound orgasmic dysfunction was less common among unmedicated individuals. One study reported that the rates of complete anorgasmia were significantly higher in patients treated with SSRIs compared to those with unmedicated depression.

While depression itself may impair desire and arousal, more severe symptoms, particularly orgasmic dysfunction and sensory blunting appear more consistently across multiple studies. These symptoms often begin early in treatment.

Risk factors

Underlying psychiatric disorder severity may be associated with higher reported rates of AISD. Potentially higher doses of medicines, prolonged treatment and polypharmacy may be influential.

Sex differences in AISD

Current evidence suggests that symptom patterns may differ by sex.

In one study, women treated with antidepressants reported high rates of reduced desire, arousal difficulties and orgasmic impairment, indicating that multiple domains of sexual function may be affected during treatment in women. Men more frequently experience erectile dysfunction and delayed ejaculation.

Comments

Antidepressant induced sexual dysfunction may involve multiple domains of sexual function. Such symptoms may overlap with the underlying psychiatric disorder.

Different doses and different SSRIs/SNRIs may differ in their sexual side effect profile.

Females and males may experience different types of sexual dysfunction side effects with antidepressants.

A limitation of this review what that it focused on antidepressants in general and not specific medicines such as certain SSRIs.

4.1.3 Selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitor use and sexual dysfunction: a pharmacovigilance analysis (Shen et al, March 2026) [21]

This study focused on the differences in the spectrum of sexual dysfunction between SSRIs and SNRIs.

The US Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS) database was analysed during the first quarter of 2021 to the fourth quarter of 2023.

Statistically significant signals were identified as those meeting all three criteria: (1) IC025 > 0, (2) ROR (reporting odds ratios) > 1, and (3) more than 3 case reports of the target drug-event in the database.

A total of 1,144,969 valid reports were included, among these were 3021 instances of sexual dysfunction. Most reports were in males.

Figure 7 shows the range of sexual dysfunction symptoms investigated for 6 antidepressants (fluoxetine, paroxetine, escitalopram, sertraline, venlafaxine and duloxetine).

It was identified that citalopram, escitalopram and sertraline had the widest range of sexual-dysfunction related symptoms. Sertraline had the broadest spectrum of sexual dysfunction.

Figure 7: Spectrum of sexual dysfunction in SSRIs and SNRIs, US Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS) database



Notes: The numbers represent the value of IC_{025} of each combination of target antidepressant and sexual dysfunction. Escitalopram in the figure represents citalopram and escitalopram.

The authors conclude that while sexual dysfunction was associated with the 6 antidepressants, the spectrum of symptoms differed.

Comments

Positive IC0.25 values were identified for a range of symptoms of sexual dysfunction across different SSRIs and SNRIs reviewed in this study.

A signal was identified for genital hypoesthesia with escitalopram, citalopram and sertraline.

There are limitations to use of FAERS including missing data, confounding and how disproportionality analysis cannot establish causal relationships.

The study may provide a high-level overview of what sexual symptoms are reported most frequently with SSRIs and SNRIs.

Due to the nature of using spontaneous reporting data, it is not known if these adverse events reported stopped or continued following discontinuation of treatment.

4.1.4 Male sexual dysfunction associated with selective serotonin reuptake inhibitors (SSRIs): A pharmacovigilance disproportionality analysis of FAERS data (Li et al, 2026) [22]

This study analysed the reporting patterns and signal strengths of male sexual dysfunction associated with 6 commonly prescribed SSRIs (fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram and escitalopram) in the FAERS database.

The distribution of 23 specific PTs was analysed. Figure 8 shows the signal of male sexual dysfunction associated with SSRIs, displaying number of adverse event signals and the corresponding ROR values.

Figure 8: The signals of male sexual dysfunction associated with SSRIs



Notes: Heatmap displaying the number of adverse event signals (A) and corresponding ROR values (B) for male sexual dysfunction association with different SSRIs.

Comments

This pharmacovigilance study describes reporting signals for male sexual dysfunction associated with SSRIs in the FAERs database.

The disproportionally signals for different sexual side effects was variable across different SSRIs.

A variety of different symptoms of sexual dysfunction was identified to be reported in males taking SSRIs. The most reported adverse event was 'erectile dysfunction' followed by 'sexual dysfunction' and 'loss of libido'.

4.1.5 Treatment-emergent sexual dysfunction related to antidepressants – a meta analysis (Serretti & Chiesa, 2009) [23]

The aim of this meta-analysis was to quantify treatment-emergent sexual dysfunction associated with antidepressants based only on selected articles that specifically investigated this type of adverse effect.

A literature search was conducted and included articles up to July 2009.

The included studies had to:

- investigate sexual functioning in patients taking antidepressants
- clearly specify that the clinicians investigated sexual dysfunction through direct inquiry or a specific sexual questionnaire
- allow only monotherapy (however one study did also include benzodiazepines)
- include only patients or perform specific analysis on a subsample of patients without previous SD
- clearly provide data on single medicines
- provide dichotomous variables for a least one outcome

Results

Primary outcome

The primary outcome measure was the rate of total treatment-emergent sexual dysfunction

Figure 9 reports the absolute percentage values and the odds ratio (OR) between medicines and placebo. Most medicines were associated with a significantly higher rate of sexual dysfunction compared to placebo. Citalopram, fluoxetine, paroxetine, sertraline and venlafaxine showed the highest rates of total sexual dysfunction.

Sensitivity analysis about these medicines focusing separately on patients with major depression did not show any significant difference.

Figure 9: Total sexual dysfunction (Serretti & Chiesa, 2009)



Notes:

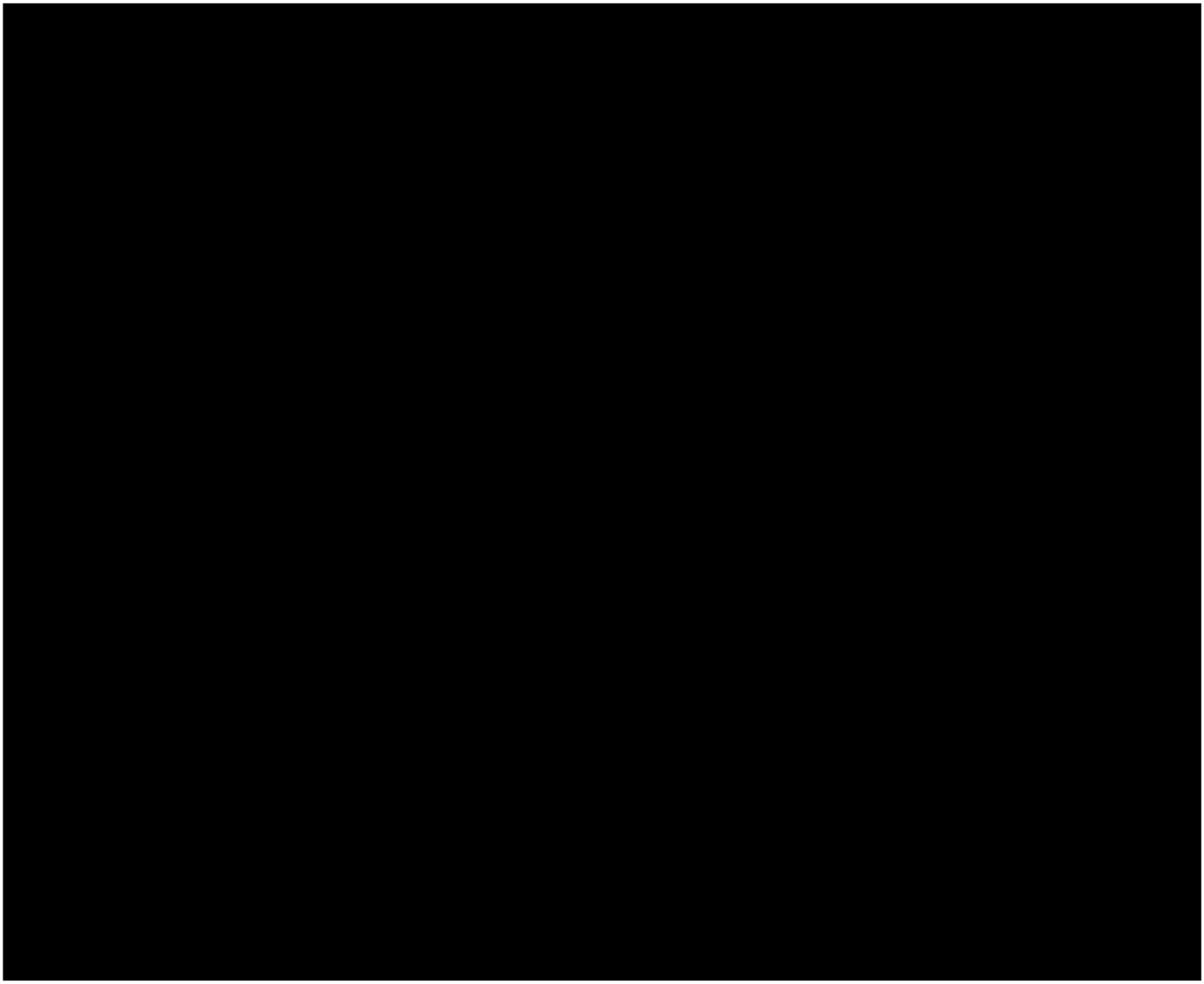
- Absolute values, 95% CI and OR compared with placebo (above each symbol) are reported.
- The number of subjects treated with a specific drug is shown between brackets.
- Ago = agomelatine; Ami = amineptine; Bup = bupropion; Cit = citalopram; Clo = clomipramine; Dul = duloxetine; Esc = escitalopram; Flu = fluoxetine; Fluv = fluvoxamine; Im = imipramine; Mr = mirtazapine; Moc = moclobemide; Nef = nefazodone; Par = paroxetine; Phe = phenelzine; Pla = placebo; Sel = selegiline; Ser = sertraline; Ven = venlafaxine.

Sensitivity analysis showed that use of different scales had a significant impact on the absolute value of total sexual dysfunction. The Changes in Sexual Functioning Questionnaire and the Psychotropic-Related Sexual Dysfunction Questionnaire were more likely to provide higher percentages, compared to the sexual effects scale and direct inquiry without any specific questionnaire.

Secondary outcomes

The secondary outcome measures were the rates of the 3 main phases of sexual response (desire, arousal and orgasm dysfunction) (see Figure 10).

Figure 10: Main phases of response (desire dysfunction, arousal dysfunction and orgasm dysfunction) (Serretti & Chiesa, 2009)



Notes:

- Absolute values, 95% CI and OR compared with placebo (above each symbol) are reported.
- The number of subjects treated with a specific drug is shown between brackets.
- Ago = agomelatine; Ami = amineptine; Bup = bupropion; Cit = citalopram; Clo = clomipramine; Dul = duloxetine; Esc = escitalopram; Flu = fluoxetine; Fluv = fluvoxamine; Im = imipramine; Mr = mirtazapine; Moc = moclobemide; Nef = nefazodone; Par = paroxetine; Phe = phenelzine; Pla = placebo; Sel = selegiline; Ser = sertraline; Ven = venlafaxine.

Separate analysis was conducted for men and women was undertaken when possible. There were very few studies providing complete data on both male and female patients, and it was not possible to provide data on all antidepressants.

For the 5 medicines included, data showed that men had significantly higher rates of desire and orgasm dysfunction compared with women, whereas women seemed to have higher arousal dysfunction than men, apart from a nonsignificant difference found for venlafaxine (Table 18).

Table 18: Percent of male and female patients with total sexual dysfunction, desire dysfunction, arousal dysfunction and orgasm dysfunction separately (Serretti & Chiesa, 2009)

[redacted]

Discussion

The meta-analysis found that citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, imipramine, and phenelzine were associated with significantly higher sexual dysfunction rates compared with placebo. The highest rates were found for citalopram, fluoxetine, paroxetine, sertraline, and venlafaxine. These medicines act on the serotonergic system.

In general, all medicines associated with total sexual dysfunction were related to significant dysfunction in every single phase of sexual response, desire, arousal, and orgasm though in different proportions.

The study found that men had significantly higher rates of desire and orgasm dysfunction compared with women, whereas women seemed to have a higher arousal dysfunction than men. A possible explanation for the last finding could be linked to the greater weight of cognitive compared with physiologic aspects of arousal in women.

The authors note several limitations in the study including limited time periods of treatment duration, different methods of investigating sexual dysfunction, limited evidence for some antidepressants compared to others, variable quality and small sample sizes in studies used.

Comments

The results of this study appear to show that different SSRIs and SNRIs may have different ranges of sexual side effects and that these may vary between males and females.

Serotoninergic medicines had the highest rate of total sexual dysfunction which was also seen when the 3 domains of sexual function were reviewed. This may suggest that SSRIs and SNRIs affect all phases of sexual function. The study did not specifically comment on the symptoms experienced within each domain noting that different symptoms can be incorporated under each domain.

A strength of this study that it included participants without pre-existing sexual dysfunction.

The outcomes should be reviewed in caution noting the limitations of the meta-analysis and how it is not clear whether other confounding such as other conditions or medicines were controlled.

4.1.6 Post-SSR sexual dysfunction

Previous review of the literature for PSSD was undertaken in the MARC report presented at the June 2026 meeting. Refer to Annex 1 for more information.

Since then, a systematic review on the topic was published and is discussed below.

A summary table of symptoms reported in PSSD in a selection of previously reviewed literature articles is available in Annex 2.

4.1.6.1 Post-SSRI sexual dysfunction (PSSD): a comprehensive review of epidemiology, pathophysiology and clinical management (Xie et al, 2026) [24]

This was a systematic review conducted up to April 2024 for studies focussing on PSSD pathophysiology, diagnostic criteria and therapeutic interventions.

PSSD's true incidence and prevalence is hard to quantify, primarily due to challenges relating to under reporting, clinician lack of awareness, and the absence of systematic long-term follow up in clinical trials.

Pathophysiology

The exact pathophysiological mechanisms of PSSD are unknown, however, multifactorial hypothesis have been proposed (see Figure 11).

Figure 11: Pathophysiological mechanisms of post-SSRI sexual dysfunction (PSSD)



1. In PSSD susceptible individuals, presynaptic 5-HT1A auto-receptors may rapidly resensitise post discontinuation, inhibiting 5-HT synthesis and release. This results in a relative predominance of inhibitory 5-HT2A signalling against overall reduced 5-HT levels.
2. SSRIs can directly or indirectly inhibit 5a-reductase and 3a-hydroxysteriod dehydrogenase activity. These enzymes convert progesterone into neuroactive metabolites, particularly allopregnanolone. Inhibition of these enzymes reduces allopregnanolone levels, weakening its excitatory effect on GABA-A receptors and causing a global reduction in GABAergnic inhibitory tone. This places the CNS in a hyperexcitable unable state, manifesting as PSSDs symptoms of sensory numbness, emotional anxiety and anhedonia.

3. Proposal that SSRI exposure induces long-term functional gene modifications in the CNS. The occurrence of chronic abnormalities in 5-HT, dopamine and neurosteriod levels may trigger widespread epigenetic remodelling. This may influence PSSD's individual susceptibility and persistence.

Clinical manifestations

PSSD symptoms may occur during treatment and persist post discontinuation or emerge after discontinuation. The clinical picture centres around persistent sexual and sensory disturbances, including genital numbness, decreased or absent libido, erectile dysfunction, orgasmic dysfunction and premature ejaculation.

Genital anaesthesia/numbness is considered to be highly specific to PSSD. Core symptoms of PSSD are outlined further in Table 19.

Table 19: Core symptom spectrum of PSSD as outlined in the review by Xie et a, 2026 (adapted)

Symptom domain	Core manifestations
Sensory disturbance	Genital anaesthesia/numbness
Sexual desire/motivation	Loss of libido/anhedonia
Arousal dysfunction	Erectile dysfunction, impaired lubrication
Orgasm dysfunction	Anhedonic orgasm, anorgasmia
Other	Premature/delayed ejaculation

Diagnosis

Diagnosing PSSD can be challenging, it may be misdiagnosed as a psychological issue rather than linked to SSRIs. A detailed and accurate history is important for differential diagnosis.

Differential diagnoses for PSSD include depressive relapse, other medicines, hypogonadism, other medical conditions and relationship/psychological issues.

Summary

The authors conclude that PSSD is a severe, underestimated persistent sexual dysfunction triggered by SSRI/SRI medicines.

The potential for persistent sexual side effects must be included into informed consent discussions prior to initiating SSRI therapy.

Raising awareness among clinicians and the public is important to avoid misdiagnosis.

Comments

PSSD is described as persistent sexual symptoms following antidepressant discontinuation, including genital anaesthesia or reduced genital sensation, decreased libido, erectile dysfunction, lubrication difficulties, and orgasmic impairment.

The evidence base for PSSD is predominantly composed of retrospective reports, small clinical series, pharmacovigilance analyses, and expert commentary.

Apart from the recent review above, no additional information was identified relating to PSSD than that previously reviewed in the MARC report (see Annex 1).

Annex 2 provides a summary of sexual side effects reported in the context of PSSD from a previously reviewed selection of literature articles.

Symptoms such as erectile disorders, erectile dysfunction, reduced or loss of libido and orgasm difficulties were reported in the context of PSSD. These symptoms are also reported during treatment.

From the current available information, it appears that symptoms of genital numbness, reduced nipple sensitivity and non-sexual symptoms (e.g. emotional blunting, anhedonia) are listed in reports for PSSD and occur after treatment discontinuation.

The potential for individual variation of sexual side effects on treatment with SSRIs/venlafaxine is possibly also seen for experiences of PSSD.

4.2 Other information

4.2.1 UpToDate [25]

UpToDate is an evidence-based point of care clinical resource for subscribers. The following information is included for SSRIs/SNRIs and symptoms of sexual dysfunction.

SSRIs are commonly associated with sexual disorder in both men and women. The following adverse reactions have been associated with SSRI use: orgasm abnormal, anorgasmia, erectile dysfunction, and decreased libido. Priapism and decreased genital sensation have also been reported with SSRIs.

Citalopram:

- *Clinical trials*: decreased libido (1% to 4%), ejaculatory disorder (6%), erectile dysfunction (3%).
- *Post market*: abnormal organism, anorgasmia, priapism (including clitoral priapism), sexual difficulty (decreased genital sensation), sexual disorder (including persistent post SSRI).

Escitalopram:

- *Clinical trials:* ejaculatory disorder (9% to 14%), decreased libido (3% to 7%), anorgasmia (2% to 6%), erectile dysfunction (3%)
- *Post market*: abnormal orgasm, priapism, sexual disorder.

Fluoxetine

- *Clinical trials:* decreased libido (1% to 11%, sexual disorder (can persist after discontinuation), ejaculatory disorder (2% to 7%), erectile dysfunction (≤7%),
- *Post market*: anorgasmia, priapism, sexual difficulty (decreased genital sensation).

Sertraline

- *Clinical trials*: decreased libido (4% to 7%), ejaculation failure (8%), ejaculatory disorder (3%), erectile dysfunction (4%), priapism (<2%), sexual disorder (males: 2%)
- *Post market*: abnormal orgasm, decreased penile sensation

Paroxetine

- *Clinical trials*: decreased libido (≤15%), ejaculatory disorder (13% to 28%), abnormal orgasm (2% to 9%), erectile dysfunction (2% to 10%), increased libido (<1 %)
- *Post market:* priapism. sexual disorder

Venlafaxine

- *Clinical trials:* Abnormal orgasm (males: ≤10%), anorgasmia (2% to 4%), ejaculatory disorder (≤10%), erectile dysfunction (5%), decreased libido (5%)
- *Post market:* priapism

Comments

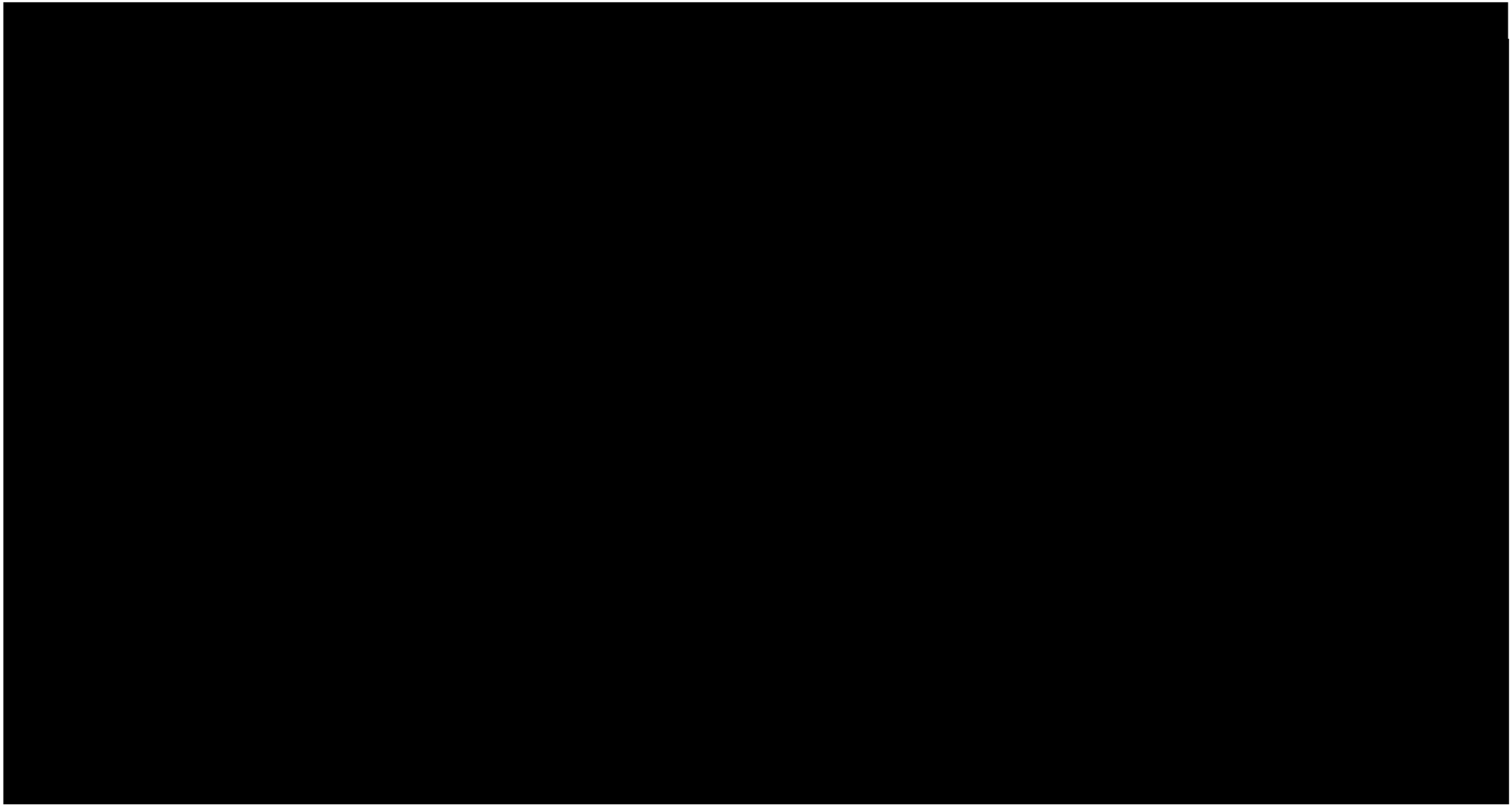
The sexual side effects listed in the product monographs the above SSRIs/SNRIs are similar to those identified above in NZ, Aus, UK and US prescribing information. Those that were not identified have been

highlighted. This includes decreased genital sensation/decreased penile sensation considered to be ADRs for citalopram, sertraline and fluoxetine.

Priapism is included as a post-market ADR for venlafaxine, which is not currently listed in the venlafaxine prescribing information reviewed above.

4.3 Spontaneous reporting







[redacted]

[redacted]



Table 21 shows the disproportionality reported for the LLT for the PT ‘sexual dysfunction’.

[redacted]



5 Regulatory action



6 DISCUSSION AND CONCLUSIONS

Sexual dysfunction is a common problem that may be experienced by individuals, particularly those with psychiatric illnesses such as depression. Sexual problems can also occur but may not be formally diagnosed as a sexual dysfunction disorder.

The term 'sexual dysfunction' is generally used to describe sexual symptoms that are classified into several sexual domains and then further classified into specific problems including being gender specific.

Sexual side effects have been reported with SSRIs and venlafaxine. The proposed mechanism is due to inhibitory effects of increased serotonin.

It appears that SSRIs/venlafaxine may affect several different domains of sexual function, and more than one domain may be affected. The most consistently reported symptoms are related to reduced sexual desire, orgasm dysfunction, erectile dysfunction and ejaculatory disorders. It may be possible that SSRIs and venlafaxine most commonly affect the orgasm domain both in males and females, particularly in females.

Most studies report overall sexual dysfunction associated with SSRIs/venlafaxine or evaluated symptoms of sexual dysfunction by domain (for example desire, arousal and orgasm) rather than specific symptoms. Studies generally report outcomes using questionnaires, interviews and sexual history taking. Variations in assessment tools, diagnostic criteria and sample sizes limits generalisation and interpretation of results.

Literature specifically reviewing sexual side effects with individual SSRIs/SNRIs is very limited. Some variation of specific sexual side effects reported with different SSRIs and SNRIs was seen in the results of the meta-analysis by Serretti & Chiesa 2009.

The data sheets for SSRIs and venlafaxine currently list various sexual side effects. Additional side effects were noted in several international prescribing information for these medicines. Some side effects listed are gender specific.

The side effect 'sexual dysfunction' is listed in some data sheets. It is unclear what symptoms this represents which may illustrate the uncertainty of specific sexual symptoms associated with each SSRIs/venlafaxine. It is also unclear if the side effect 'sexual dysfunction' represents a formal diagnosis of medicine-induced sexual dysfunction as seen in the DSM-5-TR.

Similar presentations of sexual side effects reported with SSRIs and venlafaxine may be due to other factors. Influence of biological, psychological and social factors can contribute simultaneously to the presentation. Certain individuals may be more vulnerable to sexual side effects and symptoms may differ between genders, ages or indication for treatment. For example, changes in desire have been reported in people with depression, whereas orgasm dysfunction appears more commonly reported in people with anxiety disorders.

For PSSD, the literature appears different to those that review sexual side effects during treatment. While on-treatment studies focus on the domains of sexual functioning, PSSD studies appear to include individual symptoms reported. This difference may be related to the type of studies undertaken.

Side effects relating to changes in genital sensation are not currently listed in the data sheets for SSRIs/venlafaxine. [redacted]
These symptoms were noted to not be included in the study articles reviewed within the literature section of this report but reported in spontaneous reporting. It is not known if when reported spontaneously if these symptoms occurred in people on treatment and/or following discontinuation.

[redacted]

7 ADVICE SOUGHT

The Committee is asked to advise:

- Whether the same sexual side effects (including gender-specific effects) should be listed in section 4.8 of the data sheets for all SSRIs and venlafaxine.
- Whether all the sexual side effects listed in the data sheets for SSRIs and venlafaxine could be long-lasting after treatment discontinuation.
- Whether a warning regarding sexual side effects should be the same in section 4.4 of the data sheets for all SSRIs and venlafaxine.
- Whether any communication is required other than in MARCs remarks?

8 ANNEXES

Annex 1: MARC report June 2026 meeting – Update on sexual dysfunction (post SSRI sexual dysfunction, PSSD) following discontinuation of serotonin reuptake inhibitors

Annex 2: Summary of sexual side effects reported in the context of PSSD from a selection of literature articles

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