



DRUG SAFETY UPDATE (DSU)

Antidepressants: new safety measures for all patients to improve communication of the risk of suicidal thoughts and behaviours and persistent sexual dysfunction

Specialisms: Psychiatry, General Practice, Pain management, Pharmacy, Dispensing GP practice

Summary

New safety measures are now being implemented for all patients taking antidepressant medications. This follows completion of a detailed review, involving patients and their families, into how the risks of suicidal thoughts and behaviours, and persistent sexual dysfunction are communicated in the patient information leaflets (PILs) that accompany antidepressant medications. These changes involve a new boxed warning in the PIL, a new patient card, and a supporting safety (ancillary) leaflet. The term post SSRI sexual dysfunction ("PSSD") is also being added to the PIL for some antidepressant medications.

Advice for Healthcare Professionals:

- discuss with patients when starting or changing the dose of an antidepressant or at their next review, the risk of suicidal thoughts and behaviours. Advise patients to seek urgent medical attention if they experience new or worsening feelings of suicidal intent in relation to starting an antidepressant, especially early in treatment or following dose changes
- discuss with patients when starting or changing the dose of an antidepressant, or at their next review, that there is evidence that some antidepressants¹ are associated with a risk of sexual dysfunction and that symptoms may continue after stopping treatment with certain antidepressants. Some patients refer to this as "PSSD"
- follow the relevant NICE guidance² and monitor your patients regularly after starting treatment with an antidepressant

¹ Citalopram, escitalopram, duloxetine, fluvoxamine, fluoxetine, paroxetine, sertraline, venlafaxine, amitriptyline, nortriptyline

² [NG222 \(Depression in adults: treatment and management\)](#), [NG134 \(Depression in children and young people: identification and management\)](#), [CG91 \(Depression in adults with a chronic physical health problem: recognition and management\)](#), [NG215 \(Medicines associated with dependence or withdrawal symptoms: safe](#)

- give your patient the safety (ancillary) leaflet when it becomes available in 2027 to support your risks and benefits discussions
- report suspected adverse reactions associated with antidepressants on a [Yellow Card](#)

Advice for Healthcare Professionals to Provide to Patients

- if you have new or worsening suicidal thoughts, particularly when starting or changing dose of antidepressants, seek urgent medical attention. You can call NHS 111, or your local mental health crisis team, Samaritans on 116 123, or text “SHOUT” to 85258. You can find more information and support options on the NHS website
- there is the potential for you to experience sexual dysfunction with some antidepressants, which may continue even after you stop the medicine. Please contact your healthcare professional if you have any concerns
- these are not new risks for these medicines, but it is important to be aware of them
- do not stop taking your medicine without first speaking to your healthcare professional
- please also read the patient card and the Patient Information Leaflet which contains important information about your medicine
- when it becomes available in 2027, you will also receive a supporting safety (ancillary) leaflet explaining the benefits and risks of treatment options to help you have informed discussions with your healthcare professional about taking your medicine safely
- report suspected side effects via the [Yellow Card scheme](#)

Background

A Commission on Human Medicines (CHM) Expert Working Group (EWG) on the effectiveness of antidepressant risk minimisation measures was convened in response to concerns raised by patients and their families about whether patient information leaflets (PILs) adequately communicate the risks of suicidal thoughts and behaviours, and sexual dysfunction where symptoms may continue after stopping treatment. The EWG met between May 2024 and July 2025 and their recommendations were considered by the CHM in September 2025.

[prescribing and withdrawal management for adults](#)), [CG192 \(Antenatal and postnatal mental health: clinical management and service guidance\)](#), [CG113 \(Generalised anxiety disorder and panic disorder in adults: management\)](#)

Central to the considerations of the EWG were the views of patients and families about the effectiveness of warnings in the current antidepressants' PILs. The EWG considered the views in the context of the literature published since 2019, when the regulatory position on suicidal thoughts and behaviours, and sexual dysfunction where symptoms continued were last reviewed at a committee level.

The EWG heard directly from the families of some patients and from individual patients who shared their experiences and suggestions for improvements to safety messaging.

The EWG considered the patients' and families' views on the need for additional measures to raise awareness of warnings about the risk of suicidal thoughts and behaviours, and sexual dysfunction where symptoms may continue after stopping treatment. They made recommendations to the CHM on regulatory options.

The CHM advised that updates to strengthen the wording on the risk of suicidal thoughts and behaviours in the PILs should be developed through user testing with patients representing a range of mental health conditions. The MHRA subsequently worked with the Patients Association, who brought together a focus group of patients to provide further feedback, to refine and finalise the updated wording and format of the PILs.

New measures

The Commission on Human Medicines (CHM) has advised the MHRA on several regulatory actions and the need for consistent safety messaging across the healthcare system. These include:

- A new boxed warning in the PILs to better highlight information on suicidal thoughts and behaviours, and signpost to where patients can get help.
- A new patient card available in digital or hard copy formats to reinforce key safety messages. The expectation is that the hard copy card will be designed to be credit card sized and easy for patients to carry. Initially the card will be available electronically and may be given to the patient by dispensers as an interim measure ahead of cards becoming available. A link to the electronic card will be provided in the DHPC and is also available via the following QR code:



- The term "Post SSRI Sexual Dysfunction" ("PSSD") will be added to the PILs of antidepressants associated with a risk of sexual dysfunction that may continue even after the drug is stopped¹. Some patients refer to this as post selective serotonin reuptake inhibitors (SSRI) sexual dysfunction ("PSSD"). This will better reflect the experiences of patients and help raise awareness.
- A new safety (ancillary) leaflet is being developed jointly with other healthcare system partners, to describe specific risks and benefits in more detail. This will

provide patients with specific information on the benefits, risks and alternatives for antidepressants. The leaflet is intended to be given out by the healthcare professional at the first consultation for new patients or the next consultation for existing patients. As its implementation requires collaboration across the healthcare system, the safety (ancillary) leaflet will become available in 2027.

The CHM advised several actions for the wider healthcare system on the risk of suicidal thoughts and behaviours in patients taking antidepressants. The MHRA is coordinating these actions over the coming months, which include considerations relating to updates of relevant National Institute for Health and Care Excellence (NICE) guidelines, updates to the British National Formulary (BNF) and work with the Royal Colleges of General Practice, Psychiatrists and Pharmacy, and NHS guidance.

A detailed Public Assessment Report (PAR) is now available describing the sources of data considered by the EWG in reaching their recommendations. Additionally, updates to the regulatory position and patient safety information are hosted on the [MHRA antidepressant page](#).

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#).
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

You can [sign up](#) to receive email notifications for Drug Safety Updates.

You can [sign up](#) to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- NHS England Patient Safety Team and Specialist Pharmacy Service

- Devolved Administrations
- Royal College of Psychiatrists
- Royal College of GPs
- Patients Association,
- Royal College of Pharmacy
- General Pharmaceutical Council
- Community Pharmacy England
- NICE
- Chair of EWG
- College of Mental Health Pharmacy

Article citation: MHRA Drug Safety Update volume 20, issue 3: October 2026: 1