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The BMJ

Cite this as: *BMJ* 2026;395:e101165
http://doi.org/10.1136/bmj-2026-101165
Published: 16 October 2026

Antidepressants: New safety warnings highlight risk of sexual dysfunction and suicidal thoughts

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Safety warnings about antidepressants are to be strengthened to emphasise to doctors and patients the risks of suicidal thoughts and behaviours and sexual dysfunction.

The regulator the Medicines and Healthcare Products Regulatory Agency (MHRA) is introducing the measures after a major review. This was initiated after patients and families raised concerns about the way the two key risks were currently communicated in patient information leaflets.

However, some experts said the addition of the warnings didn't "go far enough."

More than nine million people in England are estimated to take antidepressants.[1] The drugs are commonly prescribed to treat the symptoms of depression along and also other conditions such as migraine, neuropathic pain, and anxiety.

Following the review, patient information leaflets for antidepressants will be updated to include a new boxed warning signposting patients to information on suicidal thoughts and behaviours.

The MHRA said the expectation is that a new patient card will be included in or on medicine boxes to reinforce key safety messaging and help patients and carers understand how and when to access further support.

In addition, patient information leaflets for certain antidepressants will be updated to include the term "post-SSRI sexual dysfunction" (PSSD), to more clearly highlight the risk that symptoms can continue after treatment is stopped.

PSSD is a condition where people experience persistent sexual difficulties after taking certain antidepressants, which can continue even when they stop the drug.[2]

The MHRA will also develop a supporting safety leaflet with the wider healthcare system that doctors can give to patients at their first appointment discussing antidepressants. It will describe the key risks and benefits to support informed decision making.

The leaflet, which will be available in 2027, will also be given to patients who are already receiving antidepressants.

The review by the Commission on Human Medicines, an advisory body that helps inform the MHRA's regulatory decisions, assessed the latest available evidence and clinical advice and engaged directly with patients and families.

MHRA chief safety officer Alison Cave said the measures were designed to prompt "more informed conversations" about the benefits and risks of antidepressants. She said, "Antidepressants are effective medicines for the treatment of depression and other conditions.

"When used appropriately and under clinical supervision, for the vast majority of individuals the benefits outweigh the risks.

"The aim is not to discourage use, but to improve the prominence and clarity of the existing warnings."

She added, "It's imperative that patients do not stop taking these medicines without first speaking to their healthcare professional."

But Joanna Moncrieff, professor of critical and social psychiatry at University College London, was worried that the new measures don't go "far enough." Rather than leave information related to PSSD in patient leaflets, she said, the MHRA should write to all doctors to ensure they are aware of the risk and can discuss it with patients.

"The bottom line is that people need to know about this," she said.

David Cousins, chair of the psychopharmacology committee at the Royal College of Psychiatrists, added, "We welcome efforts to make information about medication, including side effects, more clear and prominent.

"Most patients for whom antidepressants are clinically indicated will benefit from their use, but, as with all medications, some will experience side effects.

"Patients should always discuss treatment options with a qualified practitioner, including the benefits, risks, and side effects, to ensure they fully understand and accept the proposed treatment."

Commenting on the measures, Chris Bird, programme manager for patient safety at the National Institute for Health and Care Excellence (NICE), said, "We are grateful to have collaborated with the MHRA on the review, with NICE colleagues joining its expert working group.

"As with all new safety advice issued from the MHRA, we will consider the implications of this advice on published NICE guidance and review our recommendations if required."

1 NHS Business Services Authority. Medicines used in mental health—England—2016/17 to 2025/26. 23 Jul 2026. https://www.nhsbsa.nhs.uk/statistical-collections/medicines-used-mental-health-england/medicines-used-mental-health-england-201617-202526

2 Reisman Y. Post-SSRI sexual dysfunction. *BMJ* 2020;368:. pmid: 32107204. doi: 10.1136/bmj.m754

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