



# Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00014**

21 January 2025

Dear [REDACTED],

Thank you for your Freedom of Information (Fol) request received on 4 January. You wrote:

*Under the Freedom of Information Act, I would like to request the following information from the MHRA:*

- 1. How many safety concerns were submitted per year to the MHRA via the Yellow Card Scheme from 2019 to 2024 concerning the drug, Citalopram (also known as Escitalopram)?*

## MHRA Response1

Citalopram and escitalopram are closely related but marketed as separate antidepressant medications.

I can confirm that a search of our database was performed for all UK spontaneous suspected adverse drug reaction (ADR) reports/ Yellow Card reports concerning citalopram and escitalopram from 01 January 2019 up to and including 17 January 2025. The result of this search can be found below in Tables 1 and 2. Table 1 shows the number of UK spontaneous suspected ADR reports and adverse reactions reported by drug per year.

Table 1: Number of Yellow Card reports and adverse event reports received 01 Jan 2019-17 Jan 2025

| Year | Citalopram             |                          | Escitalopram           |                          |
|------|------------------------|--------------------------|------------------------|--------------------------|
|      | Number of Yellow Cards | Number of adverse events | Number of Yellow Cards | Number of Adverse events |
| 2019 | 238                    | 683                      | 35                     | 127                      |
| 2020 | 199                    | 534                      | 44                     | 114                      |
| 2021 | 254                    | 696                      | 53                     | 209                      |
| 2022 | 259                    | 584                      | 81                     | 177                      |
| 2023 | 270                    | 556                      | 95                     | 204                      |
| 2024 | 275                    | 609                      | 160                    | 327                      |

Please note that the numbers for citalopram and escitalopram should not be combined as there may be reports where both substances are listed as suspect drugs.

Please note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who have had adverse reactions and so cannot be used to determine incidence rates. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular product, and may be stimulated by promotion and publicity about a product. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects

2. *What safety concern is the most predominant that is reported about the drug, Citalopram (also known as Escitalopram)?*

### **MHRA Response 2**

Table 2 shows the most commonly reported reaction for each drug and time period. The most predominant adverse event is nausea.

Table 2: The most common adverse event reported in association with citalopram

| Time Period | Suspect Drug | Reaction | Case Count |
|-------------|--------------|----------|------------|
| All time    | Citalopram   | Nausea   | 494        |
|             | Escitalopram | Nausea   | 128        |
| 2019-2024   | Citalopram   | Nausea   | 105        |
|             | Escitalopram | Nausea   | 31         |

3. *Is it safe to prescribe antidepressants (such as Citalopram) to patients under the age of 25 when there is a risk of suicide ideation?*

### **MHRA Response 3**

Antidepressants are indicated for a wide range of conditions affecting mental health. The clinical decision to prescribe an antidepressant by a healthcare professional is supported by the MHRA approved product information for each of the licensed antidepressant medicines and relevant clinical guidance.

The MHRA is responsible for ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness and are supported by clear and detailed product information which contains the relevant information to use the approved medicines as safely as possible. This includes the patient information leaflet (PIL) supplied in packs of citalopram and escitalopram available to patients and the Summary of Products Characteristics (SmPC) available to prescribers.

The information in the PIL and SmPC is intended to supplement and support the information which the doctor and then pharmacist convey to the patient in person. Some PILs can be lengthy depending on what is known about the medicine and its safety profile. All PILs follow the same format to ensure people know where to look for the information they need.

The product information for antidepressants such as citalopram and escitalopram contain warnings about the risk of suicide which was implemented following UK and European reviews of the evidence. The UK/EU review concluded that the risk of suicidal acts and behaviour is increased with the use of sertraline, citalopram, escitalopram, paroxetine, venlafaxine, and mirtazapine in patients under 25 years of age and a meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed a trend towards an increased risk of suicidal behaviour with antidepressants compared to placebo in patients aged 18- 25 years old. Please see the link

for further information.

[https://www.hma.eu/fileadmin/dateien/Human\\_Medicines/CMD\\_h\\_/Product\\_Information/PhV\\_WP\\_Recommendations/Antidepressants/PAR\\_suicidal\\_thoughts.pdf](https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Product_Information/PhV_WP_Recommendations/Antidepressants/PAR_suicidal_thoughts.pdf)

Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

The risk of suicide is greatest in the early stages of antidepressant treatment. This is likely related to antidepressants being effective only after a few weeks of taking the medicine and depression itself being an illness associated with an increased risk of suicidal behaviour. There are no marked differences in suicidal risk between the different classes and types of antidepressant. In the case of citalopram and escitalopram, this medicine is only licensed for the treatment of major depressive episode in people over the age of 18 years as the overall benefit of treatment outweighs the risk.

The current warnings in the citalopram and escitalopram PIL were extensively user tested and section 2 contains a bold headline on “**Thoughts of suicide and worsening of your depression or anxiety disorder**”. Use of emboldened text and bullet points are used throughout the PIL to highlight key safety information and action for people who experience thoughts of self-harm.

There is advice in the PIL to inform family and friends about a diagnosis of depression or anxiety as it is recognised people with depression may not have insight into their own behaviour: “**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.”

To supplement this information, the MHRA has informed healthcare professionals in the UK about the risk of suicidal behaviour associated with antidepressants via articles in the MHRA’s bulletin Drug Safety Update in April 2008<sup>1</sup> and also published guidance for prescribers on the MHRA webpage in December 2014 to summarise key safety messages<sup>2</sup>.

The British National Formulary (BNF) states, “the use of antidepressants has been linked with suicidal thoughts and behaviour; children, young adults, and patients with a history of suicidal behaviour are particularly at risk. Where necessary patients should be monitored for suicidal behaviour, self-harm, or hostility, particularly at the beginning of treatment or if the dose is changed.” The information in the product information and the BNF should form the basis of a discussion between the doctor and patient when deciding on the most appropriate medicine for them.

Clinical guidance issued by the National Institute for Health and Care Excellence (NICE) (Clinical Guideline 90, CG90) on depression in adults recommends that if a person with depression is started on antidepressants and is considered to be an increased suicide risk or is younger than 30 years (because of the potential increased prevalence of suicidal thoughts in the early stages of antidepressant treatment for this group) they should normally be seen after 1 week and frequently thereafter as appropriate until the risk is no longer considered clinically important. CG 90 advises prescribers follow a stepped-care model in which to

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<sup>1</sup> <https://www.gov.uk/drug-safety-update/antidepressants-suicidal-thoughts-and-behaviour>

<sup>2</sup> <https://www.gov.uk/government/publications/ssris-and-snr-is-use-and-safety/selective-serotonin-reuptake-inhibitors-ssris-and-serotonin-and-noradrenaline-reuptake-inhibitors-snr-is-use-and-safety>

organise the provision of services and supports patients, carers and practitioners in identifying and accessing the most effective interventions; the least intrusive and most effective intervention is provided first. More details of this stepped-care model can be found at <https://www.nice.org.uk/guidance/cg90/resources/depression-in-adults-recognition-and-management-pdf-975742636741>

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

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### **Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>