LEAP for Prescribed Drug Dependence

Lived and professional Experience Advisory Panel

LEAP4PDD Prescribed Harm Toolkit #1:

Reporting your experience of prescribed psychiatric drug harm using the Yellow Card scheme

Yellow Card Reporting: The Basics

What is the Yellow Card reporting scheme?

The Yellow Card scheme, hosted by the Medicines and Healthcare Products Regulatory Agency (MHRA), is the UK's reporting system for adverse and side effects caused by medications. The MHRA use Yellow Card reports generated by patients and doctors to monitor the safety of prescribed medications.

Who can file a Yellow Card report?

Anyone who has experienced adverse effects from taking prescribed medications can file a Yellow Card report. A medical professional, family member or friend can also file a report on your behalf.

What information do I need to file a Yellow Card report?

All you need to file a Yellow Card report is:

- Your name, email address and postcode.
- The name of the drug you took.
- A list of the side effects the drug caused.

You will be invited to provide additional information, for example about how long you took the drug for or why it was prescribed, but these are optional questions and it is entirely up to you how much additional information you choose to provide.

How long does it take to file a Yellow Card report?

You can file a basic Yellow Card report in just 10 minutes.

Why should Yellow Card reporting matter to patients harmed by psychiatric drugs?

When the MHRA receives multiple Yellow Card reports about a medication, it has the power to investigate safety issues, require updated warnings and prescribing information or even, rarely, to remove a medication from the market altogether. Yellow Card reports about prescribed psychiatric drug harm make the experiences of harmed patients visible to the researchers and clinicians who can make prescribing safer.

The more Yellow Card reports are filed about adverse effects from psychiatric medications, the harder it becomes for health authorities to ignore the reality of prescribed psychiatric drug harm.

Reporting can have a huge real world impact. In 2020, the Benzodiazepine Information Coalition encouraged thousands of patients to report adverse effects caused by benzodiazepines to the American equivalent of Yellow Card, the MedWatch scheme. As a result, the US Food and Drug Administration updated the safety warnings on benzodiazepines to reflect the risk of dependence and withdrawal.

By spending just 10 minutes filling in a Yellow Card report, you can play an important part in improving safety for future generations of patients.

Top tips for Yellow Card reporting

- Before you file your Yellow Card report, quickly jot down:
  - The name of the drug that you want to report.
  - A list of the adverse or withdrawal effects caused by the drug.

- The Yellow Card system requires you to select your side effects from a pre-set drop down menu of choices. A wide range of possible side effects are available to choose from, and you may find it helpful to type in a key word, such as 'anxiety' or 'panic', and scroll through the drop down menu choices to find the one that best describes your experience.

- Yellow Card allows you to report a number of side effects that are particularly relevant to psychiatric drug withdrawal and a non-exhaustive list of these effects can be found at the end of this document. If you have experienced adverse effects as part of withdrawal, consider reporting some of these conditions specifically. They include:

Antidepressant discontinuation syndrome	**Tardive dyskinesia**
Benzodiazepine dependent	**Withdrawal reaction**
Drug withdrawal convulsions	**Withdrawal seizures**
Drug withdrawal headache	**Withdrawal symptom**
Drug withdrawal syndrome	**Withdrawal psychosis**
Post-SSRI sexual dysfunction	

- You do not have to provide background information about the circumstances that led to you being harmed by psychiatric drugs, but Yellow Card gives you the option of providing this information if you choose. If you decide to include this information, be sure to give a clear account of why you believe the drug was responsible for causing what happened, for example by specifying that the adverse effects began shortly after starting or stopping the drug. This video by psychiatrist Dr Josef Witt-Doerring explains FDA MedWatch reporting, but it contains helpful tips for people filing Yellow Card reports too.

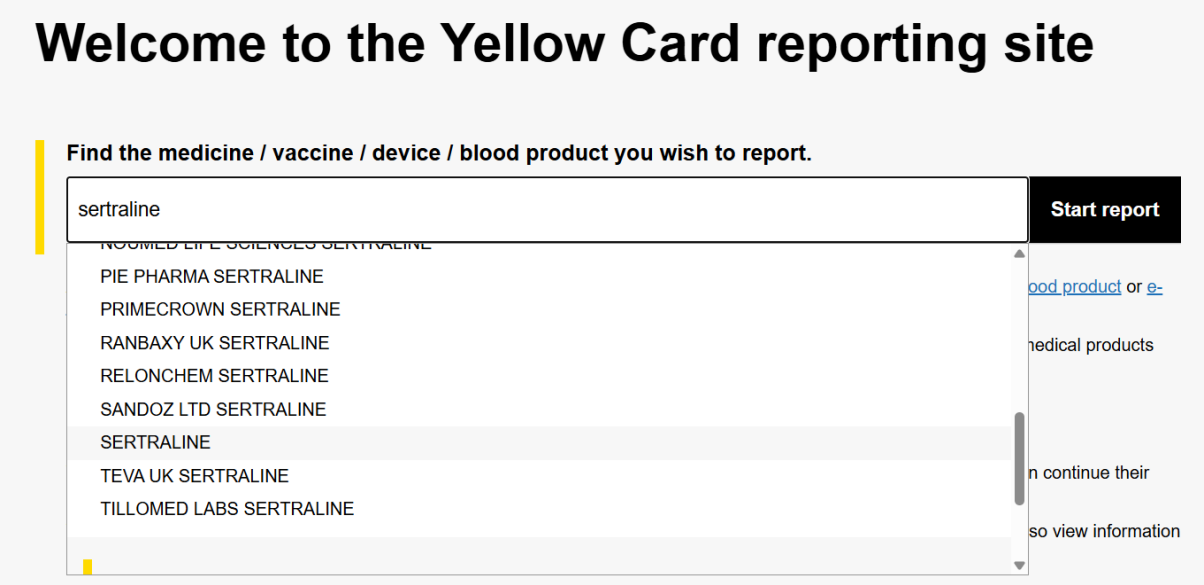
Step by step guide to filing a Yellow Card report

1) Visit the Yellow Card reporting homepage.

https://yellowcard.mhra.gov.uk/

2) Start typing the name of the drug you want to report into the search bar on the homepage.

3) Select your drug from the drop down menu. Choose the generic name if you do not know the manufacturer. For example, type 'Sertraline' or 'Quetiapine'.



4) Click 'Start report'.

5) **Question:** Are you a member of the public or a healthcare professional? Select your answer from the drop down menu.

6) **Question:** What does your report relate to?
Select your answer from the drop down menu.

7) **Question:** Who does your report relate to?
Select your answer from the drop down menu.

8) Enter your title, name, email address and postcode.

9) Enter either your initials, your sex or your age.

10) Add your side effects one by one using the 'Add' button. You can add multiple side effects for the same drug.

- Start typing the symptom you want to report into the menu bar and then select the condition that best describes what you experienced from the drop down list.
- A non exhaustive list of side effects related to prescribed psychiatric drug harm that the Yellow Card scheme allows you to report is at the end of this guide.
- For each side effect, you will be asked whether the side effect is ongoing.
- You have the option to specify when the side effect started and resolved if it is not ongoing, but you do not have to provide this information if you do not remember.

11) Rate the severity of the side effects you experienced.

12) (Optional) Explain the circumstances surrounding your experience.
    - If you're reporting a withdrawal effect, this is a great place to briefly explain that your symptoms started when you stopped taking the drug. Likewise, if the side effect you are reporting started shortly after beginning the drug you can specify this here.

13) (Optional) Explain whether you think your experience was caused by a mistake in prescribing.

14) (Optional) Provide additional, optional information about the drug you took.

15) (Optional) Provide details of any medications you were taking in addition to the drug you are reporting.

16) (Optional) Provide additional details about your medical history.

17) Click ‘Submit’ to file your report.

List of potential side effects relevant to prescribed psychiatric drug harm

Below is a non-exhaustive list of side effects relevant to prescribed psychiatric drug harm that Yellow Card system allows you to report. However, the scheme makes a wide range of options available and you may find it helpful to type in a key word, such as 'anxiety' or 'panic', and scroll through the drop down menu to find the one that best describes your experience.

Abdominal cramps	**Insomnia**
Agitation	**Irritability**
Akathisia	**Light sensitivity**
Antidepressant discontinuation syndrome	**Made anxiety worse**
Benzodiazepine dependent	**Memory impaired**
Blurred vision	**Mood swings**
Brain fog	**Muscle spasms**
Brain zaps	**Nausea**
Burning sensation skin	**Nightmares**
Chills	**Panic attacks**
Crying	**Pins and needles**
Depersonalisation	**Poor concentration**
Depression worsened	**Post-SSRI sexual dysfunction**
Derealisation	**Tachycardia (racing heart beat)**
Diarrhoea	**Tardive dyskinesia**
Dissociation	**Tinnitus**
Dizziness	**Tremor**
Drug withdrawal convulsions	**Vertigo**
Drug withdrawal headache	**Vomiting**
Drug withdrawal syndrome	**Withdrawal psychosis**
Excess sweating	**Withdrawal reaction**
Fatigue	**Withdrawal seizures**
Hallucinations	**Withdrawal symptom**