To the Medicines & Healthcare products Regulatory Agency, [mhra@mhra.gov.uk](mailto:mhra@mhra.gov.uk)

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**False information in package inserts for antidepressants about a chemical imbalance**

On 10 October 2022, the [MHRA replied](https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-10-october-2022/freedom-of-information-request-foi-22939) to people unknown to me who had raised questions about patient information leaflets (PIL) (FOI 22/939). These people had questioned the use of the term “chemical imbalance.”

The MHRA noted that the PIL for Cipramil included: “Cipramil is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness” and that this amendment followed user testing and that specific evidence to support the new phrase was not provided in the context of the user testing assessment.

For escitalopram, the PIL mentions that “these medicines help to normalize the levels of serotonin in the brain.”

For fluoxetine, the PIL mentions that “Depression is caused by a disturbance in the chemistry of your brain.”

For paroxetine, the PIL “low levels of serotonin in the brain are thought to be a cause of depression and other related conditions.”

All of these statements are wrong. It has never been shown that people become depressed because they have low serotonin or any other “chemical imbalances” in their brain. Recently, psychiatrist Joanna Moncrieff and colleagues debunked this false idea in a [highly convincing umbrella review](https://pmc.ncbi.nlm.nih.gov/articles/PMC10618090/). Moreover, the statements are very harmful for the patients who might think that if they have a chemical imbalance a drug can fix, they will need to take this drug for the rest of their lives.

I looked up a PIL this month for citalopram from [one manufacturer](https://www.medicines.org.uk/emc/files/pil.14338.pdf), and the text was “These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.”

I believe it is the duty of the MHRA to check the package inserts for all antidepressants approved in the UK and to ensure that misleading message about the cause of depression get removed in all cases.

I look forward to the MHRA’s reply. In the public interest, I have uploaded this letter on my homepage.

Best wishes



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