Medicines & Healthcare products Regulatory Agency

MHRA

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Your Ref: CP/AK/1770897

20 January 2021

Dear Mr Phillips,

**Inquest into the death of Samuel David Morgan**

Thank you for your email dated 9 December enclosing the Regulation 28 report to prevent future deaths relating to the tragic death of Mr Samuel David Morgan, aged 25 years, by self-suspension 7 days after being prescribed 10mg citalopram. I extend my sincere condolences to Mr and Mrs Morgan and the family and friends of the deceased.

Citalopram is an antidepressant that belongs to the selective serotonin reuptake inhibitor (SSRI) class of medicines. The current warnings about the known risk of suicide with use of SSRI antidepressants were implemented following UK and European reviews of the evidence. The text agreed for the patient information leaflet (PIL) was developed with patients' input and was subject to user testing.

The risk of suicide is highlighted in bold and bullet pointed in the first section of the SSRI medicines' PIL entitled "**Eight important things you need to know about ….. (the SSRI medicine)**." Specifically, this headline section of the PIL states:

- **"Some people who are depressed or anxious think of harming or killing themselves**. If you start to feel worse, or think of harming or killing yourself, see your doctor or go to a hospital straight away".

Section 2 of the PIL provides more details on thoughts of suicide and worsening depression or anxiety in bold and key messages are bullet pointed:

"**Thoughts of suicide and worsening of your depression or anxiety disorder**: If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult.

Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant. **If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.**

**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."

We have taken note of your suggestion that the "black box" warnings in the US product information of suicide warnings for patients 'would have a more immediate impact', however we are unable to find evidence that this is more effective in communicating risk than the current practice in the UK of headlines and emboldened text supported by extensive user testing to shape the presentation of key safety messages. Should new data come to light we will review this and see what changes could be made to support risk communication in the future.

To supplement the patient information, the MHRA has informed healthcare professionals in the UK about the risk of suicidal behaviour associated with SSRIs via articles in the MHRA's bulletin Drug Safety Update in April 2008 and December 2014 available at https://www.gov.uk/drug-safety-update/antidepressants-suicidal-thoughts-and-behaviour.

We also published guidance for prescribers on the MHRA webpage in December 2014 to summarise key safety messages (https://www.gov.uk/government/publications/ssris-and-snris-use-and-safety/selective-serotonin-reuptake-inhibitors-ssris-and-serotonin-and-noradrenaline-reuptake-inhibitors-snris-use-and-safety).

The GP handbook, 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.

In addition, 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. I am unable to comment on the issue of the prescription for Mr Morgan to be in contravention of NICE guidance you refer to in the report. Should you wish to follow this up please do contact NICE directly or raise with the General Medical Council.

We are grateful you for notifying us of this tragic case. We have used this information to generate a Yellow Card report with the reference number ADR 24541651-001. Yellow Card reports help us to continuously monitor the safety of medicines. if you or the family wish to submit further information, please use this reference number to ensure it is added to the appropriate case.

Yours sincerely

Dr June Raine
Interim Chief Executive
Medicines and Healthcare products Regulatory Agency