On Sunday, 2 August 2015, 0:24, "Jureidini, Jon (Health)" <Jon.Jureidini@sa.gov.au> wrote:

Dear Dr Loder
Thank you for your prompt response. I am sorry that I have taken a while to respond, as I have been off-line. We have responded to your requests in the attached document.

We are confident that any remaining concerns can be sorted out in the copy-editing phase.

It would be wonderful to hear from you by Monday morning Adelaide time.

Jon Jureidini
On behalf of 329 RIAT team

<see attached Response to Loder 2.doc>

From: onbehalfof+eloder+bmj.com@manuscriptcentral.com [onbehalfof+eloder+bmj.com@manuscriptcentral.com] On Behalf Of eloder@bmj.com [eloder@bmj.com]
Sent: Saturday, 1 August 2015 9:48 AM
To: Jureidini, Jon (Health)
Cc: jo.lenoury@btopenworld.com; nardo.mickey@gmail.com; david.healy54@googlemail.com; Jureidini, Jon (Health); melissa.raven@flinders.edu.au; catalin.tufanaru@adelaide.edu.au
Subject: BMJ - Decision on Manuscript ID BMJ.2014.022376.R5

31-Jul-2015

Dear Prof. Jureidini:

Manuscript ID BMJ.2014.022376.R5 entitled "Restoring Study 329: A randomised, controlled trial of the efficacy and harms of paroxetine and imipramine in the treatment of adolescent major depression" which you submitted to BMJ,

Dear Prof. Jureidini,

Thank you for your patience. I've spent the day going over the paper and reconciling it with previous versions.

I have some remaining minor requests. I will be checking my queue over the weekend so if you can make these changes quickly we may be able to have an acceptance decision before next week begins.

* In the methods section can you please indicate who decided how to allocate adverse events into system organ classes (SOCs) when doing the MEDdra coding? It isn't

obvious why anorgasmia, somnolence, drug withdrawal and insomnia have been allocated to the psychiatric SOC. Is this specified by MEDdra or is it a matter of judgment? If so, whose was it? It is also not clear what is meant by the terms "toothache dystonia" and "sore throat dystonia" which are in the nervous system SOC. These things are in table iv in the appendix.

* Figure 3 is new and I am not sure why it has been added. I apologise if you have explained this somewhere and I missed it. This doesn't seem in line with the objective of sticking with the original objectives of the study. It also isn't obvious where the FDA data can be found -- can you please add a reference? This table would seem better placed in the appendix.

* Several of the tables in the appendix include "SOC" as a column heading. Can you please specify whether this is the "primary" SOC? For column headings that currently say "MEDdra term" could you please specify whether the term you provide is a lowest level term, a preferred term, a high level term or a high level group term.

* Figure 2 is very small and hard to read. I cannot easily make out what the numbers are for the confidence intervals, for example. Please provide the actual numbers, eg point estimates with 95% CIs, for the 8 week outcome for both LOCF and MI either here or in the text of the paper.

Elizabeth Loder

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