Reviewer’s report

Title: Analysis of spontaneous reporting of suspected adverse drug reactions for non-analgesic over-the-counter drugs from 2008 to 2017

Version: 0 Date: 14 May 2019

Reviewer: Andrew Thompson

Reviewer's report:

I read the manuscript "Analysis of spontaneous reporting of suspected adverse drug reactions for OTC drugs from 2008 to 2017" with interest. In its current form, however, I am unable to clearly understand the analyses performed, and therefore the appropriateness of the methods used and the interpretation of the findings. There are also several other factors that would improve overall quality.

1) The use of absolute values does not account for stratum-specific proportions. Firstly, 'anchoring' the results to a per X of the population in each year (e.g. /1,000 of the population) accounts for variation in the overall number of people 'at risk' of an ADR. This would also be beneficial for future comparisons. Secondly, the use of chi-square is limited. Using stratum-specific proportions from the relevant population distributions would enable the calculation of risk ratios and associated 95% CI. I would also caution against the use of chi-square when the numbers in one or more outcomes is small, Fisher's exact test is more appropriate in these situations.

2) Following the above - Table 2 and any similar reworking should contain an extra column for statistical outcomes. This would aid interpretation of the results.

3) I question the decision to omit analgesics from this study. a) It would provide a better overall assessment of the burden of ADRs due to OTC drugs; b) The previous analysis went up to 2014, meaning there is 3 years' additional data available.

4) There is no justification provided for stratifying patients as per Figure 2. Furthermore, in which group do people aged 70 fall? It would also be interesting to explore if there are any common patterns in suspected causal drug and concomitant drugs - i.e. evidence towards drug-drug interactions.

5) Supplementary extension of Table 1 would be informative.

6) The writing is generally acceptable, but there is room for improvement in terms of flow and scientific style.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

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