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: 28 May 2019

Reviewer: Beate Garcia

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Referee comments on PHAT-D-19-00084

Analysis of spontaneous reporting of suspected adverse drug reactions for OTC drugs from 2008 - 2017

Thank you for letting me read this article with important findings regarding OTC drugs. I do think that this article should be published, even if I believe that the limitation mentioned first (underreporting) is so crucial that there is a huge potential that the pictures drawn up by this research project is totally wrong. However, this we cannot control, which necessitates further research in this area also in the future.

Overall comments

– Please go through the text and correct for grammar mistakes (was/were), commas and incomplete sentences. Especially in the method and result section, language could be improved.

– Throughout the manuscript, be aware of use of the term ADR vs ADRs. Many places where ADRs is applied, I believe the single form (ADR) is the appropriate. E.g. line 59 and line 60 (page2).

Abstract

Introduce the abbreviation ADR the first time you use the adverse drug reaction term.

Methods

– Line 79: I wonder about the identification of OTC drugs. You state that the trade names of the OTC drugs are different from the trade names for prescription drugs. In my country, this is not the case. Please confirm that this is always the case in Croatia. If not, this is a bias of the study.

– In Line 188 you also state that the trade names were extracted in November 2018, which may have introduced a bias as there is a possibility that OTC drugs could have changed names in the examined period. I wonder, why did you not go back 10 years and identify trade names that had been used in the study period? And included these? Please explain.

– Line 82. It seems like only the serious ADRs have been included, but I do not think it was like this? Please specify that also non-serious were included. This will also be important to mention in the result section and in Table 2.
Results

– In Table 2, why is only the 5 most frequently involved drugs mentioned? They represent only about 28% of the reports. Please justify this choice.

– Line 117: you mention the most frequently reported ADRs. I wonder if you saw any difference between the ADRs classified as ‘serious’ vs. those classified as ‘non-serious’? What is the implication of your findings?

Discussion

Line 134: That most ADRs were classified as non-serious should be more clearly stated and shown in the result section.

Line 149: It could be interesting for the reader to learn some examples of the educational interventions that have been proposed on student- and professional level to increase awareness of pharmacovigilance. Please mention some examples.

Line 166: Please mention examples of the multiple conditions that correlated with multiple OTC drugs, or rewrite the sentence to be meaningful.

Conclusion

Please do not conclude on items you have not studied. E.g. you know that the number of consumer reports has increased, but have not studied the awareness.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

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.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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Needs some language corrections before being published

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