Author’s response to reviews

Title: Do newly marketed generic medicines expand markets using descriptive time series analysis and mixed logit models? Korea as an exemplar and its implications

Authors:

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Version: 1 Date: 19 Feb 2016

Author’s response

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A) General

We wish to thank all three anonymous referees for their constructive comments. Almost all of the comments and suggestions have been incorporated into the revised manuscript, which we believe is significantly improved as a result. We have provided a response to each of the comments below.

B) Reviewer #1

1. Why does the title end with a question mark? I think it is a typo.

Author comments:

Thank you – we will revised the title will be “Do newly marketed generic medicines expand markets? Korea as an exemplar and its implication”
2. Lines 4-5, page 2: please explicit for the first time the abbreviation NHI (see also lines 17-18 and 21).

Author comments:
Thank you - This has been revised.

3. Line 4, page 3: please add a description of provider characteristics in Korea (i.e., tertiary general hospital, general hospital, hospital, clinics). It may be useful for a foreign reader.

Author comments:
Thank you – we have now added details of medical institutions.

4. Lines 7-8, page 3: please join the word "nature".

Author comments:
Thank you – now rectified.

5. Line 27, page 3: please add "tertiary" at the end of the line, to avoid confusion between types of medical institutions.

Author comments:
Thank you - This has been revised. Since general hospitals are also considered tertiary hospitals, we amended tertiary general hospitals into teaching hospitals.

6. Lines 30-33, page 3: this sentence sounds redundant. I suggest replacing "Unlike previously treated users [...]" with "To sum up, compared with previously treated users [...]".
Author comments: This has been revised as the reviewer commented.

7. Line 47, page 3: please add a parenthesis after "(see Figure (a)".

Author comments: Thank you - This has been revised.

8. Lines 58-59, page 4: I would not use the word "influenced", as it implies causality. I suggest rephrasing the sentence as follows: "Demographic and socioeconomic status were not significantly associated with generic [...]".

Author comments: This has been revised as the reviewer mentioned.

9. Line 31, page 5: the sentence is badly written. I suggest rewriting as follows: "As mentioned, there is an increasing trend across countries [...]".

Author comments: Thank you - This has been revised as suggested.

10. Table 1: please add "N(%)" also after the subheading "Major comorbidities".

Author comments: This has been revised as suggested.

C) Reviewer #2

1. Quality of written English is, to my view, not suitable for publication and should be reviewed integrally. As an example, the title in itself "means something", but "says something different".
Author comments:

Thank you – we have now been through the paper and edited where necessary. We hope this is now acceptable.

2. Methods and their application are also confusing. Time series analysis would be helpful here if observational data previous to patent expiry were included, allowing for interrupted time series analysis. This would permit a more robust analysis of trend changes and substitution effects. But even so, sample size (717 patients) also raises concern about the relevance and consistency of the findings.

Author comments:

Thank you - We preferred to analyze the factors contributing to the increase in the utilization. We’ve already published papers with a time series analysis showing the trend of drug utilization. In this study, we wanted to investigate the phenomenon surrounding generics more in detail. Consequently, we used mixed logit model. We hope this is acceptable.

3. In the discussion, to my view, assumptions (or speculations) about quality of prescription - rational use of drugs and incentives underlying prescribing decision making - should be made, if to be made, with extreme caution. Also linking generic entry with inadequate use of drug is to my opinion to be deeply reviewed - as market expansion, in lack of demand side measures, is not a problem of generic entry but of any new entry (see effects of new on-patent launches in diabetes, copd, cardiovascular prevention, etc) worldwide.

Author comments:

You are right. In the future, we’d like to examine the market expansion effect with other medicines/ medicine classes such as newly entered drugs and also generics in other disease, as you mentioned. However - we’ve started with generic statins. We hope this is acceptable.

D) Reviewer #3

Thank you so much
Author comments: Thank you very much for this endorsement!

E) Editorial requests

1. Ethics:

Author comments:

Thank you - Ethics for this study was not required as we used aggregated anonymised data. We describe the reasons in the manuscript and some references (these can be expanded upon including references from BMC Medicine and other articles, etc. We hope this is acceptable.

2. Consent:

Author comments:

Not applicable (as 1), i.e. dealing with consolidated anonymised utilization data – so do not need patient consent (similar to other numerous published studies involving anonymized aggregated health authority/health insurance data that we have been involved with). We hope this is acceptable.

3. Availability of supporting data:

Author comments:

Thank you for this - We added Availability of Data and Materials section saying that the dataset can be available by requesting for academic research. We hope this is acceptable.