Author's response to reviews

Title: Can authorities appreciably enhance the prescribing of oral generic risperidone to conserve resources?: findings from across Europe and the implications

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Can authorities appreciably enhance the prescribing of oral generic risperidone to conserve resources?: findings from across Europe and implications


Dear Ursula and colleagues

Thank you for the helpful comments from the two reviewers. We believe we have now adequately addressed these as we would still very much like BMC Medicine to consider publishing our cross-national comparison study reviewing the influence of the limited demand-side activities undertaken by health authorities among Western European countries following the availability of generic risperidone and their impact. As mentioned, the objective was to provide direction to health authorities and health insurance companies in mental health disease areas in the future as more standard drugs become available as generics. This is because there is a recognised need among health authorities to tailor pharmacological treatments in schizophrenia and bipolar disease. In addition, there have been concerns regarding generic drugs in these disease areas highlighted in previous publications regarding generics that I reviewed for BMC Medicine.

As seen in the manuscript, we have previously published some of the single country studies to assess whether the changes in risperidone utilisation patterns post generics were significant or not in the respective country. However as previously mentioned, we used a different approach in this cross country comparison. This was based on % changes in risperidone utilisation before and after generics. We used this approach because generic risperidone was available at different times among the selected countries. In addition, the population size as well as the characteristics of the databases varied among the countries. However, the single country studies helped provide robustness to the findings from the cross national comparison to help provide future direction. We believe this novel approach worked as there was remarkable consistency in the findings. As a result, we believe we can draw robust conclusions - especially when combined with findings from the other countries and regions studied (Austria, Spain – Catalonia – and NHS Bury).

The findings suggest that there is little ‘spill over’ of learnings encouraging the prescribing of multiple sourced products in a class once available. As mentioned though, this is tempered in this situation by the recognised need to tailor pharmacological treatments in these complex disease areas as well as differences in the effectiveness and side-effect rates between the different pharmacological treatments. We believe this is an important finding. Our findings also suggest that there would be limited impact from any demand-side measures to encourage the preferential prescribing of multiple sourced atypical antipsychotic drugs, which we believe is another important finding. In addition, there appears to be no concerns with the prescribing of generic risperidone as seen for instance by high rates in Scotland and Sweden. However as seen and mentioned by the reviewers, there is an appreciable difference in the pricing of generic risperidone and its utilisation vs.
the originator between countries, with the opportunity for some to reap additional savings with further highlighted measures.

We also highlight the need for physicians to factor in the side-effects of antipsychotics when choosing treatments. This substantiates our comments that treatment needs to be tailored to individuals.

Consequently, we hope BMC Medicine will be interested in publishing the revised manuscript to guide potential future activities among health authorities and health insurance companies. We also believe our findings will be of interest to a wider audience.

Finally, I can again confirm that all authors contributed to the manuscript and that all tables and figures are originals. We have also not submitted this paper to other Journals for consideration. In addition, I have now moved the author contributions to earlier in the manuscript as directed.

Details of author contributions are as follows (mentioned in the manuscript using their initials only):

- B Godman, AE Finlayson, E Raschi and C Barbui devised the concept for the paper and produced the first and subsequent drafts. B Godman is the guarantor of the paper supported in the scientific content by E Raschi and C Barbui
- M Petzold performed the statistical analyses and critiqued successive drafts
- K Bennett, M Bennie, A Bucsics, A Martin, M Persson, J Piessnegger, S Simoens and C Zara provided the utilisation and expenditure data for their respective countries as well as details of the various demand-side measures. They also critiqued successive drafts.
- All authors read and approved the submitted manuscript

I have also inserted that no ethics approval was needed or obtained since we utilised only aggregated drug utilisation data was used without access to specific patient date.

I look forward to hearing from you.

Yours sincerely

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