Reviewer’s report

Title: Influence of mandatory generic substitution on pharmaceutical sales patterns: a national study over five years

Version: 2 Date: 3 August 2007

Reviewer: Jane Robertson

Reviewer’s report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

I note that this work forms part of a larger project and is linked to other publications. However, this paper needs to be able to be read ‘stand alone’ and therefore needs additional information to make a number of aspects of the paper clearer to the reader unfamiliar with the larger project.

1. I feel there needs to be a re-ordering and clarification of some of the background information, including clarification of the meaning of substitutable (para 1). Some of the explanation occurs in the methods section and could be moved to the introduction. Elsewhere in the manuscript there is reference to ‘medically equivalent’ and ‘substitutions restricted for medical or regulatory reasons’. A short paragraph explaining the terms and application of substitutions in the Swedish context would be helpful to the reader.

2. The final sentence in paragraph 1 is unclear.

3. Reference is made in the introduction to decentralisation which occurred in parallel to the generic substitution policy. It would be helpful to the reader for the expected implications of this decentralisation to be described (some of this occurs in the discussion).

4. The statement on page 6 is unclear: “… and document reports on performed substitutions sent by the pharmacies”

5. The methods section needs to make it clear whether the analyses are based on sales data rather than prescriptions (is mentioned in the discussion). Page 8 begins “prescribed pharmaceuticals in the selected therapeutic groups encompassed by the PBS that were dispensed between January 2000 and 30 June 2005 were included in the study.” Later in the same paragraph it states that “data compromised volumes sold expressed as DDDs”. It is unclear if the age stratifications used are based on prescription volumes known to be supplied to these age groups (would imply prescription level data were available) or population adjustments.
6. It is unclear why having stated that nucleosides and nucleotides were unaffected by the reform that the authors then chose to use this category of drugs to explore age/gender variations in substitutions.

7. I think the discussion would benefit from being shorter and more directed, with key points clearly defined and using reference to key results.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Text needs general revision for correction of some English and avoidance of repetition of terms in sentences e.g. in methods section “… their status as substitutable or non-substitutable and when substitutable substances became substitutable.”

2. Needs to be consistency in presentation DDD/1000 and day, DDD/tid or DDD/1000/day using an accepted standard.

3. I think some rewording of the text describing the results of the study would make the paper a little easier to follow. There are few quantitative measures of changes, no formal time series analyses and reliance on terms such as ‘proportionally higher’, ‘largest volumes’. Perhaps there could be some comment as to why formal analyses such as time series analyses were not performed.

4. Figure 3 appears to have the data for males and females 45-64 years repeated instead of the second set being data for 64-75 years old.

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Discretionary Revisions (which the author can choose to ignore)

1. The authors may wish to consider adding an additional line to the graphs in figure 1, showing the total prescribing by class, then substitutable and non-substitutable drugs below. Then the reader would have a clearer sense of trends over time and relative impact of the substitution policy.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a
statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.