Reviewer's report

Title: The Impact of Regional Co-payment and National Reimbursement Criteria on Statins use in Italy. An Interrupted Time-Series Analysis.

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Reviewer: Gabriel Sanfélix-Gimeno

Reviewer's report:

The study aims to evaluate the impact of national and regional cost containment measures on statin use in Italy using appropriate design and methodology. Although it is not novel, is of importance in its field and its findings bring some light regarding the effect of drug reimbursement policies in a specific setting.

Major Compulsory Revisions

- Throughout the manuscript, statements regarding the effect of the policies measured are too suggestive of a causal link between observed prescribing rates and the policies (e.g. “The revision of the AIFA Note in November 2004 caused a remarkable reduction in the upward trend of statin use”). It should more clearly express that a temporal association was observed, that may or may not have been causal.

- In the abstract, the “conclusions” paragraph should be limited to the conclusions drawn by the study results. The study was not designed to compare different drug reimbursement policies; therefore, the statement “The restriction to reimbursement Interventions had a greater impact on consumption than the regional co-payment” should be avoided. The conclusion should be based on their results: the national revision of the reimbursement criteria was associated with an immediate drop and a decrease in trend of statin use, while the regional copayment was associated with a small increase in trend of statin use.

This commentary also applies to the manuscript conclusions.

- In the last paragraph of the introduction section, the aim seems to be redundant. It should read: The aim of this study was to evaluate the impact of the national and regional cost containment measures on statin use in Italy during the period May 2001 – December 2007.

- In the results section the authors make interpretations of some of the results (i.e. “the effect of the copayment was overall negligible”). Authors’ interpretations of the results should be avoided in this section, which should be restricted to the presentation of the findings.

- Further limitations should be addressed. One of the most important limitations of the study resides on its observational nature. Observational studies do not allow establishing a cause-effect relationship; many other events happening simultaneously may have influenced prescribing patterns during the span of the study.
- The methodology used to address the main objective is appropriate, however, it should not be pointed as a strength of the study. It is expected that appropriate methods to address the research questions are used.

Minor Essential Revisions

- In the Methods section, Statistical analysis subsection, the descriptive analysis should be further detailed (descriptive analysis by regions with and without copayment, descriptive statin use trends plot, etc.)
- In Figures 1 and 2, the title of the y-axis should be written in English (that is, DDD/1000 inh. day). Also the heading of both figures should be more appropriately written. It should state: Monthly statins consumption (DDD/1000 inh. day) in the two groups of regions.
- In Figure 1, a footnote explaining the meaning of the arrows should be added.
- Although the language is generally acceptable, it needs some language corrections before being published.

Discretionary Revisions

- In the third paragraph of the results section the authors describe the selection of the model. Maybe this part would fit better in statistical analysis subsection of the methods section.
- In Table 2, authors included all the parameter estimates from the segmented regression analysis. However, the estimates for the dummy variables included are not very informative and make the table larger and harder to read. These estimates may not be necessary.

Level of interest: An article of importance in its field

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