Reviewer’s report

Title: Review of risk sharing schemes for pharmaceuticals: considerations, critical evaluation and recommendations for European payers

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Reviewer: Libby Roughead

Reviewer’s report:

I think this paper addresses a really important topic in an area where there has been very little work published. I suspect this paper has the potential to add significantly to the literature in this area. However, in its current presentation I think the paper is perhaps too ambitious and with insufficient structure to achieve this purpose.

My main concerns are with the methods section and presentation of results. While the medline search is appropriately described. The description of the search of the grey literature is poor and requires more description. I think it insufficient to say you just went to websites you knew of.

What is most lacking in the methods, and thus in the results though, is how the information was then structured and synthesized. I think it would really help this paper if you provided definitions of your categories in your methods section - what is the definition of PVA used, what about caps and what about outcomes. Then I think you should indicate how you decided which examples fitted each definition (eg one author only, multiple authors independently). I say this as I am most familiar with the Australian system and none of the examples presented in table 1 for Australia are examples of what is considered in Australia a price volume agreement. Price reduction at the time of listing is not considered a price volume agreement - but rather the negotiated cost-effective price. Price volume agreements in Australia, are related to a reduction in the price once the volume exceeds the expected maximum market for the cost-effective indication (meaning use has extended into the market where the product is not cost effective at that price ). I am not sure where the information came from that companies typically provide free drugs on our section 100 scheme - I don't believe this to be true (the example presented is rare, not “typical”. In the Abacavir example, it was the company only asking the PBAC to pay for 2 of 3 supplies, not that that PBAC would only fund 2 of 3 and this comes about because of companies not wanting to drop global floor prices - I don't think this to be a true price volume agreement - hence the importance of definitions. The lack of definitions makes it difficult to know what is truly being compared across countries and I also think it important in the tables to identify when something applies to the whole country (such as Australia with one national system) as opposed to parts of a system eg the US.

The headings in the results and discussion section should match the aims and I can't see this to be the case. Throughout the results and discussion there are
phrases such as "There are concerns" - these need to be identified much more rigorously - consumer concerns, industry concerns, payer concerns - is it just an opinion of a member of the payer group or is it a formal statement from the payer. Similarly, the criticisms - stakeholder criticisms?? Is this a valid way to assess a risk sharing scheme? What about health and economic outcomes?

Also in the results section are "we propose" "we believe", bits of results and case studies. I think if you untangle this to results first, case studies as illustrations if you wish, but then linked back to overall synthesis, with recommendations in the discussion, the structure would be improved. Also in the results are statements such as "as discussed" which actually refer back to information in the tables, not information which is appearing earlier in the text. This makes it very difficult for the reader to follow. The authors also make recommendations, but it is hard to see, upon which evidence this is based and it would be stronger if this could be made clear.

I do think this is a really important and there is a lot of useful information gathered, but I think it currently not if a format that provides enough rigour to be helpful to the debate.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I am a member of the drug utilisation sub-committee of the Pharmaceutical Benefits Advisory Committee - which oversees one of the systems assessed by this paper. I have no other conflicts to declare