Reviewer's report

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

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Reviewer: Paul V Grootendorst

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Traditionally, drug plans entered into relatively simple contracts with drug manufacturers. The drug plan reimbursed the manufacturer at a fixed rate per unit dispensed to plan beneficiary. Increasingly, these simple contracts are being supplanted by more elaborate contracts. These more elaborate contracts include so-called “price-volume” contracts in which the price paid per unit varies with the number of units dispensed. One example is a “hard budget cap” scheme wherein the price paid per unit drops to zero once price times volume exceeds some pre-specified amount. Another example of a more elaborate contract is the so-called “pay for performance” (PFP) scheme wherein the price paid per unit depends on the clinical status of the beneficiary receiving the drug. Typically prices are higher if the patient realizes some clinical improvement after taking the drug.

The present papers enumerate some of these contracts entered into by pharmaceutical firms and private and public drug plans in the EU, Canada, and the USA. It claims that such non-standard contracts must be used into the future in the EU so as to “enable the continued provision of comprehensive and equitable healthcare.” It provides some commentary on the success of these more elaborate contracts and provides some guidance to policy makers considering their use.

Major Compulsory Revisions

My overall impression of the paper is that a suitably revised version could be a useful contribution to the literature. However, as it currently reads, the paper is too disorganized. It requires some focus and structure. Moreover, it needs to consider the effects that the various contractual schemes have on the incentives of drug developers in producing effective new therapies. The section of the paper “Definitions and legal status ” can be safely integrated into other sections. There is little value in the paragraph beginning “In some countries such as Poland, new laws are needed before risk sharing schemes can be fully enacted”.

The authors might consider the following structure:

Why the non-standard contracts?

This would position the contracts as providing advantages to both parties relative to standard contracts. Example: a PFP – a scheme wherein reimbursement is
paid conditional on clinical success – can provide value for money to payers while allowing drug companies to demonstrate their drug’s value in ways that are not possible using clinical trial data.

Desirable features of non-standard contracts between drug plans and drug companies.

This would consist of a set of normative criteria, suitably justified, with which to evaluate the contracts. For instance, one criterion would be verifiability: it is possible for both parties to the contract to verify whether patient health outcomes have improved (in the case of performance based contracts). Another is credibility: there are mechanisms that ensure both sides to the party live up to their end of the bargain.

What kinds of non-standard contracts have been struck between drug plans and drug companies?

This is largely already covered in the tables and accompanying text.

What are the predicted and actual outcomes of these contracts?

What is the predicted success of these contracts (predicted according to the extent to which they meet the normative criteria?) What is known about actual success of these contracts in achieving outcomes?

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