Reviewer's report

Title: Why the MDGs need Good Governance in Pharmaceutical Systems to Promote Global Health

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Reviewer: Barbara Mintzes

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This is a very well written commentary that addresses an important issue, governance and corruption in the pharmaceutical sector. It provides an excellent rationale and overall is a pleasure to read, as well as doing a very good job of representing the importance of attention to governance within this sector.

I had a few suggestions for changes, all of which I would consider 'minor essential revisions'.

1. A discussion of governance within the pharmaceutical sector needs to include the influence of pharmaceutical promotion, and specifically fraudulent marketing and disguised marketing, and its influence on medicine prescribing and use. This is only alluded to in a very non-specific way in the inclusion of delivery of medicines among the aspects that need to be considered. The recent legal cases in the US concerning fraudulent marketing, including repeat violations and fines in the billions of dollars, cannot be left out of the picture in an analysis of governance in this sector. Specific aspects of governance may be mostly relevant to lower and middle-income countries; others are highly relevant in high income countries as well as within both the private and public sectors in middle income countries, and the private sector in the lowest income countries. Do issues such as continuing medical education that is disguised promotion, market seeding trials, and ghostwriting, or selective publication, biasing the scientific evidence, fit under the rubric of governance in this sector?

Many of the activities that have surfaced in the US legal cases are criminal. There are similar patterns of prescribing and of physician 'key opinion leader' activities in other countries, but no legal remedies thus far. Are specific mechanisms (such as financial support for whistleblowers) needed in this sector in order to ensure adequate governance of delivery of pharmaceuticals to the end user, the patient.

2. It is not clear how the specific good governance initiatives listed in this paper were chosen. Is this a comprehensive list of international agencies' initiatives?

3. I found the information provided on the effects of each of the initiatives fairly broad and non-specific. It would be very helpful to include concrete examples of successful changes in a specific country and perhaps involving specific medications and/or services.
4. There are statements in the discussion for example of 'strong results' for GGM and MeTA without any bar provided for what might be considered a weak, moderate or strong result, or whether there were also significant barriers to effectiveness.

5. The discussion on challenges is an important part of the paper but again it would be useful to include specific examples.

The discussion of the global political economy dimensions appear to hint at the power imbalances that can occur between a low income government and wealthy donor countries that support the interests of their industries and/or of the industries themselves. I don’t know which aspects are being considered. More direct discussions and some examples again of how this is playing out would be helpful.

**Level of interest:** An article of outstanding merit and interest 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 have no financial competing interests. I do not receive any funding from the pharmaceutical industry.

I am a Board Member for Health Action International's European network (HAI-Europe). Health Action International (HAI) is currently providing the secretariat for the Medicines Transparency Alliance (MeTA), which is discussed in the commentary. Although the European network (e.g. HAI-Europe) is not directly involved, both are part of the broader international HAI network.