Reviewer’s report

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

Version: 2 Date: 6 January 2014

Reviewer: Barbara Mintzes

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The article reads very well and addresses an important issue very well. I felt that the main concerns that I raised previously were addressed.

I have several minor essential revisions to recommend, mainly for clarity:

1) “Historically, illegal pharmaceutical marketing in the United States has been uncovered by whistle-blowers and have revealed practices that led to increased drug costs, biasing or misrepresenting scientific evidence/education, and direct risks to patient safety through illegal off-label promotion” [4, 5]

   - Whistleblower legislation enabling the large pharmaceutical fraud cases is a relatively recent phenomenon (I am not sure ‘historically’ is correct). Public Citizen’s detailed report is likely to be helpful; otherwise just delete ‘historically’.

   - also this line hints at the likelihood that the US cases were possible because of this enabling legislation with whistleblower protection. This may not be clear to readers – it is an important point in terms of governance because the same practices may be occurring (are occurring, if sales figures are any indication) in other industrialized countries but cannot be challenged due to differences in legal frameworks. It raises a general point in terms of the importance of structural changes, if implemented and monitored, in ensuring better governance.

2) P7: “In the past decade, available research has provided increasing evidence that when good governance is absent, there is greater vulnerability to corruption and health gains suffer.”

   - I would suggest rewording ‘and health gains suffer’ to something like ‘… limiting access to needed medicines and health services.’ (the examples below this sentence refer to these situations. It wasn’t clear if the Burkino example was related to medicines specifically or health services.)

3) P8: “Good governance approaches and absence of corruption in both the public and private pharmaceutical sector are crucial in maintaining adequate distribution of essential medicines for populations who lack access, preventing diversion/theft of pharmaceuticals, and ensuring that medicines are safe and not otherwise falsified or otherwise made intentionally dangerous.”

   - I am wondering what is meant by ‘otherwise made intentionally dangerous’. Is this a reference to promotion for off-label uses? To inadequate labeling for
example of serious adverse events or contraindications or other regulatory oversight? If so this should be specified. Also there are many examples of access to unsafe medicines via corruption when the medicines are not “made intentionally dangerous”. A recent example includes conflicts of interest in the US FDA advisory committee that decided to keep more birth control pills that are more hazardous but no more effective on the US market.

4) P12, top of page: You mention areas of greatest improvement. In which areas was there less success to date?

5) P12: MeTA – it would be useful to add at least one line stating one result from MeTA, to make this section more consistent with the other initiatives that are described. If this is not possible, a statement that it is moving from the pilot to the next phase is all that is needed. The first mention of results is in the points from the U4 paper (in the discussion) that state that Jordan and the Philippines were successful (presumably more successful, with other countries less successful but no details provided on either cases).

6) P17: you state that changes in conflict of interest policies in selection of essential medicines and drug procurement policies are less measurable. These would still be measurable – one could look at the decisions made pre- and post-policy shifts, with a control group of countries or units without such policy changes - but the approach used might need to be more complex than in cases of procurement (in fact I’m not sure this is the case as I suspect this is also complex).

7) Discussion:

The need for initiatives to be country-led is an important point made in the discussion. This is an important point but also a more complex one than is suggested. A related issue is that smaller and lower income countries may have a GDP that is much smaller than that of a single major multinational pharmaceutical company. Do you have any suggestions for how national governments might be protected from undue private sector influence? This problem affects both higher and lower income countries, and can also affect trade negotiations that limit national autonomy.

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 do not have any financial competing interests. I am a member of the Board of Health Action International (HAI-Europe). HAI's global office is the secretariat for MeTA. This is an indirect non-financial competing interest, as HAI-Europe and
the MeTA secretariat operate out of the same office, although as a board member for HAI-Europe I have no involvement in oversight of the MeTA work.