Reviewer’s report

Title: Why European and US drug regulators are not speaking with one voice on anti-influenza drugs: regulatory review methodologies and the importance of "deep" product reviews

Version: 0 Date: 12 Jul 2017

Reviewer: Larry Sasich

Reviewer’s report:

The authors are commended for their excellent work. This manuscript is particularly important in developing countries that have limited drug regulatory authority resources.

Comments follow:

Page 4 Line 8

Suggest that the term "giant" be replaced with a more neutral or objective term such as company, firm, or corporation.

Page 4 Line 27

Readers have no way to determine if any group or individual is truly independent regarding potential or real conflicts of interest. Authors or groups frequently self describe their work as independent. Suggest that "independent" be removed and that determining true independence is problematic.

Page 5 Line 56

"We also propose that persistent uncertainty and knowledge deficits regarding NIs could have been ameliorated had regulators proactively engaged in a public debate".

Suggest brief mention of the FDA's legal authority and potential political barriers to the agency participating in a public debate, presumably with other national drug regulatory authorities.

The FDA has the legal authority to determine if a sponsor has submitted substantial evidence that a drug will do what is claimed in the professional product label. The Food, Drug, and Cosmetic Act does not contain provisions that would allow the agency to participate with other national drug regulatory authorities in a public debate on the quality and methods of a new drug review. Such debates would require additional economic and personnel resources that the FDA does not have and are unlikely to have under its new administration even if it had the legal authority.
The FDA because of the Freedom of Information does provide the materials available for public debate by patients, clinicians, and policy makers in the form of freely available regulatory as were provided in this manuscript. Free publically available FDA regulatory documents may contain rigorous analyses of unpublished clinical trials and other analyses conducted by the agency.

Page 6 Line 39

A brief definition of "grey literature" may be helpful that includes publically available drug regulatory authority documents.

Page 15 Line 36

"… but see authors, forthcoming”. See no additional reference to this statement. Is there a plan for an additional study?

Page 19 Line 12

The -0.25 day point estimate does not appear in Table 1.

Page 30 & 31 Lines 51 -10

See comments for Page 5 Line 56. In addition to legal authority for the FDA and international drug regulatory authorities is the transparency of drug regulatory authorities outside the FDA. Do other international authorities allow access to drug reviews similar to Sweden and the US?

Page 33 Line 7

FDA regulatory reviews are required to be made publicly available by law for years. Medical reviewers, journal editors, and clinicians must accept some responsibility for the under utilization of these documents.

Level of interest
Please indicate how interesting you found the manuscript:

An exceptional article

Quality of written English
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Acceptable

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