Joint Committee on Vaccination and Immunisation

Protocols for vaccine manufacturer engagement with JCVI sub-committees

JCVI Secretariat

August 2015

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The JCVI agreed in June 2014 that it would be appropriate for some JCVI sub-committees to receive presentations from manufacturers to inform them on specific topics relevant to the work of the committee. The decision to engage with manufacturers will be taken on a case by case basis in response to the particular information needs of individual sub-committees. The engagement of vaccine manufacturers with sub-committees is a move designed to ensure a sub-committee has an opportunity to critically assess the most up to date (and often unpublished) information about vaccines being considered. The purpose of this paper is to set out the process for this engagement to ensure transparency and that it does not damage the reputation of the JCVI, or allow manufacturers to influence, or be seen to influence the decision making of the sub-committee or the JCVI.

Information provided in confidence will be treated accordingly and will only be made available to the membership of JCVI, members of relevant sub-committee(s), and Government officials. The JCVI is subject to the provisions of the Freedom of Information Act, and manufacturer submissions should clearly indicate data regarded as not suitable for release, and the reasons for this in line with exemptions applicable under the Act. Such reasons may include data being ‘Pre-publication’ (referring to s.22 FOI Act ‘information intended for future publication’ or s.41 ‘information provided in confidence’) and 'Commercial' (referring to s.43 ‘commercial interests’).

The following practises will be observed in preparation for and undertaking of sub-committee meetings where manufacturer representatives may be invited to present information.

1. The sub-committee will decide in advance of each meeting whether their discussions might benefit from the provision of information held by vaccine manufacturers.

2. Where it is agreed the discussions of the sub-committee may benefit from the provision of information held by vaccine manufacturers, the sub-committee will decide upon the nature of scientific information they wish to be appraised of, which will be confirmed by the sub-committee Chair to the secretariat.

3. Each relevant manufacturer will be invited to provide this information to the sub-committee. Where the topic is relevant to more than one manufacturer’s product, each manufacturer will be given equal opportunity to provide that information. The chair of each sub-committee will decide whether there is sufficient expertise (either from members or observers) to critically assess the information presented and to question the scientific representatives of the manufacturer.

4. Information provided to the Sub-committee in written form should not exceed ten pages of A4 in Arial font size 12. Written appendices may also be submitted, where agreed in advance with the secretariat. Written information and presentations should be provided to the secretariat at least two weeks ahead of the date of the meeting at which they have been invited to present. Information provided in confidence should be marked accordingly.

5. Manufacturer scientific representatives must only present information requested by the sub-committee. Should a manufacturer believe additional information may be of use to the sub-committee; this should be outlined in writing to the secretariat at least four weeks before the meeting. The sub-committee Chair will decide in advance of the meeting whether such information is of import, and may therefore be additionally presented.

6. No more than three representatives from a manufacturer may attend to present at any meeting and confirmation / names of who will attend must be provided at the time of submission of the presentation (point above). All those attending should be there to present relevant data and studies and be able to answer any questions at the time of the meeting. For example those whose primary role is research, development, health economic modelling and regulatory. Representatives should not be employees whose primary role is associated with any aspect of commercialisation, communications or corporate affairs. There may be a limited opportunity to follow up after the meeting with supplementary information.

7. Each manufacturer shall be given a set amount of time to present to the sub-committee. The sub-committee will then have a dedicated time to question the representative(s), to discuss the content and to post additional questions which can be answered later. At the end of the agenda time manufacturers will leave and the meeting will continue. Manufacturer representatives will not be allowed to participate in sub-committee discussions around any decision or in the development of any conclusions, either at the meeting or otherwise. No manufacturer will be made aware of the findings of the sub-committee meeting in advance of their publication in the relevant minute in accordance with normal JCVI practice.

8. The agenda for all sub-committee meetings will be published online two weeks prior to the meeting and will clearly indicate which companies, if any, have been invited to present and the issues to be considered.

9. Following presentation at a sub-committee meeting no company should issue any press release or statement which could be seen to imply influence over the workings of the sub-committee or the JCVI.

Manufacturers should not expect to be invited to attend sub-committee meetings. The JCVI and its secretariat may choose to amend and/or re-publish this document at any time without notice.