



COMMISSION ON HUMAN MEDICINES

Chairman: Professor Stuart Ralston

Ms Joanna Wood
Independent Medicines and Medical Devices Safety Review
Room 3.25b Shepherd's House
King's College London
London SE1 1UL

3rd July 2019

Dear Ms Wood,

Thank you for your letter of 26 June offering me the opportunity to respond to comments made by Mrs Lyon, Chair of the Association for Children Damaged by HPTs at an oral hearing on 20th May. As before, as Chair of the Commission on Human Medicines (CHM) I will address any points relating to its work and have asked the MHRA to address issues relevant to its secretariat function.

With respect to the work on the ROBINS-I methodology by two experts in the Group that the Commission set up to review the publication by Heneghan et al. (referred to in Passage 1), this was declared at the start of the meeting and is transparent in the published minutes¹. Since the terms of reference of the Group included consideration of the utility of the Newcastle Ottawa Scale to assess study quality, I consider it would have been remiss not to include those with specific expertise in this area.

The summary of the publication by Heneghan et al. that was provided to the Expert Group and CHM by the secretariat² clearly described the potential biases and confounding factors in the studies included in the meta-analysis (Passage 3).

Finally, Passage 4 refers to the need for a 'truly independent' process. It is the Commission's duty to maintain independence and impartiality at all times and a strict code of conduct is in place to ensure this. When the CHM recommends

¹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/799931/Final_signed_minutes_-_CHM_ad_hoc_expert_group_on_meta-analysis_of_oral_HPTs_redacted.pdf

²https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/799874/CHM-Ad-Hoc-Expert-Group-paper_Heneghan-meta-analysis_March-2019_redacted.pdf

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that an ad hoc Expert Group is established, the membership is selected based on the knowledge and expertise required to evaluate the data in question in addition to considering any potential conflicts of interest in determining the appropriate membership.

I hope that these clarifications are helpful. My thanks again for providing me with a right to reply.

Yours sincerely,

Professor S Ralston

Chair of Commission on Human Medicines

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