Dear Eloise,

Please find below GlaxoSmithKline's comments on the Assessment Group (AG) report on the treatment of influenza.

We would firstly like to recognise the excellent job the assessment group have done, despite the very difficult data sources and circumstances surrounding the report. We do however have some additional comments.

Page 28 - The assessment group report does not mention that zanamivir is licensed for use in influenza prophylaxis, or that it is being assessed for this indication in the ongoing influenza prophylaxis review (http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11736) (although the ongoing review is referred to).

Page 36 - The report states that studies with healthy volunteers who were treated for experimentally induced influenza were excluded from the analysis. We feel a better approach would have been to include these patients in the healthy adults subgroup, to lend additional strength to the analysis.

Page 44 - We feel the use of Intention To Treat analysis as the default, in this case may have been inappropriate. Given the differing levels of 'true' influenza in trials, this will override any differences between treatments, meaning a better default analysis in any future reports would be the ITTI population. However this concern is addressed later in the report when detailing the importance of the 'true' attack rate and the construction of the model.

Page 52, 55, etc. - The report refers to patients with 'COAD', however in current clinical practice the preferred term is 'COPD' (http://www.nice.org.uk/guidance/index.jsp?action=byID&o=10938)

Page 69 - The report states there appear to be no 'clear difference' between zanamivir and placebo in the particular subgroup. Given 4 out of 5 point estimates show a reduction in length of illness (including the largest of the trials), a more appropriate phrase would be 'statistically significant', as is used throughout the report.

Page 217 - On the difficulty of running a head to head placebo controlled trial, we would like to add that given the different administration methods, this would need to have a double dummy, and if an attempt is made to compare the use of inhalation powder with tablets on adverse events, three different placebo arms would need to be included (and have the problem of practical unblinding).

If you have any comments or questions surrounding our comments, please do not hesitate to contact me.

Kind Regards,

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[redacted]

GlaxoSmithKline

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