Email response

Dear Ella and Lori,

Just a couple of comments on the ACD:

Para 4.12, second bullet point: "for people with a pseudophakic lens, the company presented a comparison of dexamethasone intravitreal implant with ranibizumab in its base-case and with bevacizumab and watch–and–wait as a scenario analysis":
Minor factual error: you need to add "laser" in the scenario analysis.

Para 4.20 (and actually my comment refers to the whole recommendation): "The Committee considered the cost effectiveness of dexamethasone intravitreal implant compared with fluocinolone acetonide intravitreal implant for people who have a pseudophakic lens and DMO that has not responded adequately to non-corticosteroid therapy, or such treatment is unsuitable for them [...] it considered that the cost effectiveness of dexamethasone intravitreal implant is likely to be similar to fluocinolone acetonide intravitreal implant".
Has the Committee taken into account that the company's comparison is for the TOTAL POPULATION and not the pseudophakic one? Have the results for the TOTAL POPULATION been used as a proxy for the pseudophakic population? I note that fluocinolone has higher rates of cataract requiring extraction in phakic patients (see ERG report, page 214). This means that the fluocinolone outcomes in the total population have been more negatively affected by cataract formation compared with dexamethasone, so may in fact be more effective than dexamethasone (and not similar to it) in the pseudophakic population.
I think this point may need to be discussed further and clarified in the FAD.

many thanks,
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