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Chairman Rt Hon Greg Clark MP
Chair of the Science and Technology Committee

12 February 2021

Dear Chairman Rt Hon Greg Clark,

Thank you for your queries.

The low dose/standard dose schedule (LD/SD) was used in one of the AstraZeneza (AZ) trials. However, both the MHRA and European Medicines Agency (EMA) have only provided regulatory authorisation for the use of the standard dose/standard dose schedule. The initial Lancet paper described a higher eventual efficacy of the low dose/standard dose schedule but the reasons for that finding at the time were not understood. Subsequently, further exploratory analyses by the Oxford University team found that it was the extension of the dose interval (the LD/SD participants all had a longer dose interval) that provided the higher vaccine efficacy. Therefore, whilst JCVI considered the LD/SD schedule, there is no good basis to take that option forwards at this time, and it would not be possible under current Regulation 174 anyway which only allows administration of the vaccine exactly as authorised. Using a LD as the first dose also may not be as good a first dose as SD, in terms of the protection gained in the period between doses.

The unpublished data from AZ has now been released as a pre-print in The Lancet. They have also been submitted as a paper for peer-reviewed publication. The pre-print can be found here: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3777268.

The Pfizer, AZ and Moderna vaccine trials are all on-going trials. Data are continuing to accumulate and in the background, there are numerous analyses being conducted as close to real-time as possible. Therefore, there are multiple iterations of datasets that are constantly being updated. At various points, early results are being shared. I think it is important that the Committee understands the very dynamic nature of the trials, analyses and reporting of results. The fact that investigators are willing to share unpublished or interim analyses with expert scientific groups is a sign of collaboration and trust. Publication of fuller results (usually when early signals are more precise) usually follows any sharing of initially unpublished results. Therefore, to your question: “are there any data from Pfizer or

AstraZeneca trials that have not been published"?, the simple answer is yes, but these are on-going trials.

Best wishes,

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