



Public Health England

Protecting and improving the nation's health

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Sent by post and email: norman.lamb.mp@parliament.uk

Dear Mr Lamb

We will be writing to you and colleagues regarding the report the Science and Technology committee have issued today. However, in the meantime, I would like to respond to your comments on Twitter regarding PHE's reporting of clinical trials. We acknowledge that we have not complied with EU legislation.

We are sorry and we are working to put this right as quickly as possible. As you rightly note, these rules exist for good reason. We should be compliant and the data for these trials should be on the EU Clinical Trials Register (EUCTR).

In your tweets, you asked about our quote to journalists on today's report. It was necessarily short to fit the space available in media articles, and we are sorry this was unclear. Results for the two completed studies have been published in open access articles, and we are in the process of uploading the results to EUCTR. The final study's data and results are still being analysed. I have put full details on the three trials in question below for completeness.

Trial Title: A phase 2, open-label study of the safety, tolerability and immunogenicity of a Novartis meningococcal B vaccine when administered at a 0, 2, 6 month schedule and of a single dose of Novartis meningococcal ACWY conjugate vaccine in healthy adults aged 18-65 years.

This study has been completed and the results published here:

<https://www.sciencedirect.com/science/article/pii/S0264410X15006593?via%3Dihub>

There is a link to these study results in a clinicaltrials.gov entry here:

<https://www.clinicaltrials.gov/ct2/show/NCT00962624?term=NCT00962624&rank=1>

Trial Title: A Phase IV, randomised study to evaluate the immune response of UK infants receiving DTaP/Hib/IPV, meningococcal C conjugate and pneumococcal conjugate vaccines, antibody persistence and responses to booster doses in the second year of life.

This study has been completed and the results are published here:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2643544/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2812092/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3067384/>

The results are linked to on a clinicaltrials.gov entry here:

<https://clinicaltrials.gov/ct2/show/study/NCT00625677?term=NCT00625677&rank=1>

Trial Title: A phase III/IV randomised open-label study and comparison of the immunogenicity and safety of a single adolescent booster dose of a meningococcal group C conjugate-containing booster vaccine (Meningitec™, or Menjugate™, or NeisVac-C™, or Menitorix™), when given concurrently with an acellular pertussis-containing booster vaccine (Repevax™ or IPV-Boostrix™)

This study has been completed but results still being analysed and have not been published. We recognise that this should have been done already in order to comply with the rules.

We are sorry that the data is not yet on EUCTR and fully committed to publishing it on the register. I acknowledge that publishing results in academic journals is not the same as uploading the full data and we are working on this as a matter of priority.

Best wishes

Yours sincerely

A handwritten signature in black ink, appearing to read "Duncan Selbie". The signature is written in a cursive, flowing style.

Duncan Selbie
Chief Executive