The MHRA Papers - Part 7

There's a lack of crucial data, but not to worry - the clock is ticking.

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JAN 13, 2025

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SUMMARY: We are not sure about the potency of the stuff, RNA doing its own
the risk of anaphylaxis, Astra Zeneca's use of polysorbate or their lack of data on
severe cases or the elderly, but apart from that everything is OK and secret, of co

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We continue our review of the minutes of the meeting of the MHRA's Commissi
Human Medicines (CHM) COVID-19 Vaccines Benefit Risk Expert Working Gro
which took place on 17 December 2020.

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This very well-attended meeting (lots of secret members on the secret list or secr
squirrels) discussed all three vaccines in contention for the prize of first to get th
conditional market authorisation.

The Pfizer BioNTech vaccine batches did not appear very stable, with the mmRN
going off to do its own stuff in the vials:

> The EWG discussed the low level of RNA integrity in the Emergency Use (EU) batches a why they are lower than that seen in the CT batches as there appears to be no clear rea for this difference. The EWG considered shearing (non-intact RNA particles) as a poss reason for the low RNA integrity. The EWG heard that the EU batches are close to the e of failure at release in terms of the RNA integrity specification. The EWG heard that R integrity decreases with decreasing stability. The EWG considered whether a loss of R integrity will lead to a reduction in immunogenicity.

Potency was different between what the manufacturer measured and what the National Institute for Biological Standards & Control measured. Why that arose impossible to say: the assay used is secret (i.e. its name is redacted at the end of p of the minute).

The EWG then considered how to benchmark the risk of anaphylaxis and waffle about comparing anaphylaxis to the background rate of adrenaline use in Canada according to a 2002 paper or perhaps comparing it to the rate following influenza vaccination.

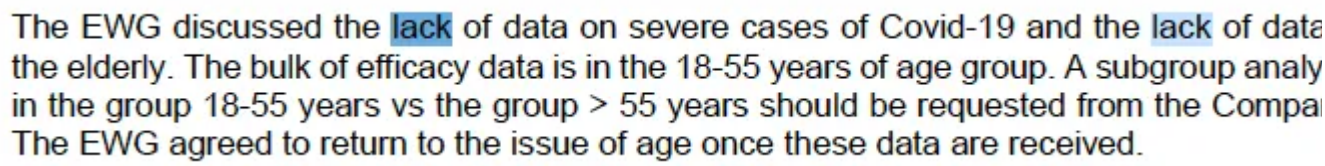
Next, the EWG considered the ~~Oxford~~ Astra Zeneca's AZD1222 trial data.

Dosing was discussed, and "effectiveness" data met the WHO standards, but furt on the EWG suggested there was uncertainty between antibody response as a co of protection.

Also

> The EWG agreed that as the vaccine contains polysorbate the company should be as for further details around the cases of anaphylaxis that occurred with the AZ vaccine. EWG heard further safety data (e.g. narratives and listings) will be received 21 Decem 2020. The EWG heard that over 1000 cases are in the age range 65 years and over for safety data.

And:


The EWG discussed the lack of data on severe cases of Covid-19 and the lack of data
the elderly. The bulk of efficacy data is in the 18-55 years of age group. A subgroup analy
in the group 18-55 years vs the group > 55 years should be requested from the Compa
The EWG agreed to return to the issue of age once these data are received.

There was also a lack of information on the interruption of transmission from asymptomatic cases. But apart from the lack of data, everything else was OK.

A final paragraph mentioned the Moderna vaccine undergoing testing in the US.

This post was written by two old geezers who think the lack of crucial data on a s to conditional approval may be - a bit of a - problem.

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Stephen Due 7d *Edited*

The word "secret" should be an absolute red flag in medicine. A century ago the BMA was op what were called "Secret Remedies". Times have changed. It looks like secrecy is now OK with

powers-that-be in medicine. Any reason that sounds good will be trotted out - "commerical-i

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Vivian Evans 7d

Another bundle of information 'from the horse's mouth' which leaves me speechless! So 'Teh Authorities' still had doubts in their meeting of 17th December 2020 - after (!) the first British were being already vaccinated, with great fanfare.

IAW, this was driven by politicians who screamed 'follow the science' while disregarding, nay into the dust that same science. You couldn't make it up ...

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