The MHRA Papers - Part 13

The heavily formatted secret minutes

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SUMMARY: We report on the most common expressions used to examine and d the evidence. The most common was "The EWG heard," but we do not know wh them what. Secrets are forever. Do not look for "analysed." It's not there.

Before continuing our review of the meeting minutes of the MHRA's Commissio Human Medicines (CHM) COVID-19 Vaccines Benefit Risk Expert Working Gro which took place on 29 January 2021, we would like to point out some interesting

We searched the 19 EWG formerly secret minutes (but heavily redacted in places relating to the content of the meeting from 25 August 2020 to 3 January 2021. Th the period leading up to the release of conditional market authorisation (CMA in speak) on 21 December 2020 and its UK counterpart on 1 January 2021. This proc is called mutual recognition in regulatory speak. In the case of biologics, all registrations are handled centrally by EMA.

This, however, is only the legal authorisation to market a product under specific indications and restrictions; it is not a recommendation.

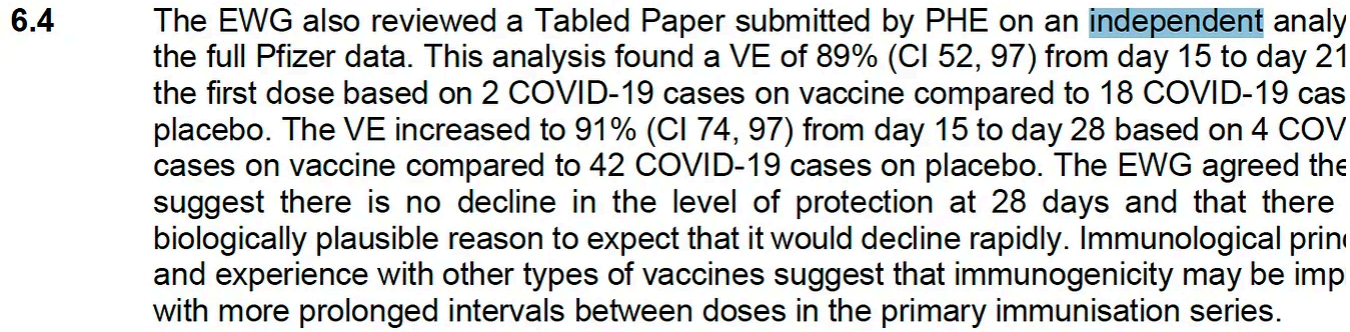
The EWG task was to examine the evidence of the effectiveness and harms of the Covid vaccines.

This is a public service of the most significant importance given the time contex

Going through the formerly secret minutes, we noticed particular quirks about th minute taking.

So, we searched the files for specific repetitive phrases. Here is what we found:

- "The EWG heard that".....was cited 390 times in 17 files.
- "The EWG noted that".....was cited 183 times in 16 files.
- "The EWG agreed that".....was cited 92 times in 11 file
- "The EWG discussed".....was cited 65 times in 12 files.
- "The EWG analysed".....was cited 0 times.
- "The EWG remarked".....was cited 0 times.
- "The EWG asked".....was cited 17 times in 3 files.
- "The EWG queried".....was cited once in 1 file.
- "Evidence" was cited 21 times in 10 documents.
- "Verify" was cited once in 1 file.
- "Statistical" was cited 12 times in 8 files, but it referred to the manufacturers analysis.
- "Independent analysis" was cited once in 1 file dated 24 December 2020:



6.4 The EWG also reviewed a Tabled Paper submitted by PHE on an independent analy the full Pfizer data. This analysis found a VE of 89% (CI 52, 97) from day 15 to day 21 the first dose based on 2 COVID-19 cases on vaccine compared to 18 COVID-19 cas placebo. The VE increased to 91% (CI 74, 97) from day 15 to day 28 based on 4 COV cases on vaccine compared to 42 COVID-19 cases on placebo. The EWG agreed the suggest there is no decline in the level of protection at 28 days and that there biologically plausible reason to expect that it would decline rapidly. Immunological prin and experience with other types of vaccines suggest that immunogenicity may be imp with more prolonged intervals between doses in the primary immunisation series.

The term "Presentation" was cited 70 times in all 19 files. One reason for this fre use is the law enacted by the chief secret squirrel, who reminded attendees that t could not take notes or copy the presentations.

This implies that no time was allowed for analysis or reflection before or after th meeting.

The results could be due to poor note-taking, as the voices of those who had dou about any of the subject matter were not recorded except once. All were anonym and the impression is one of a tightly controlled secret procedure.

None of the queries or questions are detailed (we know the EWG had 36 questior and none of the discussions are sufficiently detailed to reconstruct a timeline (wl was cited six times in four documents). None of the minutes allow us to understa evolution of the evidence base from Phase I to Phase III trials.

This post was written by two old geezers who discuss, analyse, ask, and query everything. They do not usually note stuff, but they sometimes hear and seldom a unless they have examined and discussed the evidence.

Discussion about this post

Vivian Evans 2h

Your analysis of the expressions used is pretty devastating. However, for me the most importa stumbling block is the 'advice by the chief secret squirrel', prohibiting note-taking of presenta Every student of biological sciences got drilled into them that extensive note-taking is a must the age of all those EWG squirrels allows one to conclude that they must have been taught th very much that they all had such brilliant memories that they were able to recall precisely the those presentations. Obviously, with no notes and only recourse to something remembered c arguments can easily be swept off the table: 'no proof', or 'that's not what was said' ...

So can we say that the EWG was a bunch of yay-sayers, engaged in not rocking the boat but veneer of 'scientific endeavour' to the proceedings?

How much were they being paid for attendance, btw?

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Myra 2h

Interesting X-post by Esther McVey. Does she subscribe to TTE too?

She posted yesterday about a debate in parliament regarding the failings of the MHRA. Appa debate was last Thursday.

In the post she also refers to the disappearance of the minutes of the Vaccine Benefit Risk Exp Working Group. At least the debate will be recorded in Hansard....

(Does anyone know how to copy and part images in comments?)

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1 reply

4 more comments...