FOI 23/302

MHRA RESPONSE
25 JULY 2023

Dear

Thank you for your email.

> *Please can you provide me with the answer to the following questions.*
>
> *When you first gave the Pfizer COVID vaccine it's emergency use licence, did it comply with the legal efficacy percentage of 50%?*
>
> *When you first authorised AstaZenica COVID vaccine, did it comply with the legal efficacy percentage of 50%?*
>
> *As of today, do the Pfizer COVID vaccine and AstraZenica COVID vaccine hit the 50% efficacy threshold required to be authorised as a vaccine?*
>
> *What is the documented and proven efficacy of the AstraZenica and Pfizer COVID vaccines.*
>
> *If either of the Covid vaccines are below the 50% efficacy threshold, why haven't you removed the licence?*

The relative risk reduction, as expressed by the vaccine efficacy, is the usual scale considered when looking at the performance of a vaccine. The absolute risk reduction from a particular study is a difficult figure to interpret, as it is influenced by factors such as the transmission setting at the time of the study i.e., the level of infections at the time of the study, and other characteristics of the study such as the follow-up duration. This can be illustrated by looking at the data from the BioNTech-Pfizer vaccine, as shown in the table below. The data in the table are taken from the SmPC for Comirnity which can be found at the following link - Comirnaty - Summary of Product Characteristics (SmPC).

Symptomatic infections 7 days after dose 2

	Vaccine group	Placebo group	Absolute risk reduction	Vaccine efficacy
Pfizer initial analysis	8/17411 (0.05%)	162/17511 (0.93%)	0.88%	95.0%
Pfizer updated analysis	77/20712 (0.37%)	850/20713 (4.10%)	3.73%	91.3%

At the time of the approval the absolute risk reduction was 0.88% (which could be stated as 114 people being vaccinated to prevent one infection). Updated data were subsequently provided after further follow-up and the absolute risk reduction was 3.73% (which could be stated as 27 people being vaccinated to prevent one infection). However, it would not be right to say that the updated data showed better efficacy, it is simply that with extended follow-up the overall infection rate was higher, meaning that the same effectiveness of vaccine will give a larger absolute risk reduction. With additional follow-up the infection rates would have increased further, and the absolute risk reduction would have been greater. Therefore, it is not considered that these calculations of absolute risk reduction are useful in isolation for understanding the performance of the vaccine.

For Vaxzevria the efficacy information can be found in the Summary of Product Characterisation:
Summary of Product Characteristics for Vaxzevria - Last update February 2023 - GOV.UK (www.gov.uk)

We have published PARs for all of the authorised vaccines, as have the EMA. These PARs clearly show MHRA's and the EMA's assessment of the vaccines and how the benefit/risk (including the efficacy of the vaccines) was determined. Further to this, the clinical data submitted for each vaccine has been published by the EMA. Links to these are provided below.

https://products.mhra.gov.uk/
https://clinicaldata.ema.europa.eu/web/cdp/home
https://www.ema.europa.eu/en

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Please remember to quote the reference number above in any future communications.
If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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Yours sincerely

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