FOI 22/1117 – quantification of 'safe' and 'effective'

REQUEST
17 November 2022

Can you please supply:

- the metric or standard that is used by the MHRA to quantify the term "safe" with regards/reference to a "covid vaccine" authorised for use by the MHRA?

- the metric or standard that is used by the MHRA to quantify the term "effective" with regards/reference to a "covid vaccine" authorised for use by the MHRA?

MHRA RESPONSE
12 February 2023

Dear

Thank you for your email of 17 November 2022. Please accept our apologies for not having responded before now.

There is no 'metric or standard' used by the MHRA to quantify 'safe' in terms of a COVID-19 vaccine, or any other medicinal product. No medicine is completely risk-free. For a medicine to be considered acceptably safe, its expected benefits should be greater than any associated risks of harmful reactions. This can be determined based on the data submitted with an application for a marketing authorisation for a medicinal product such as a COVID-19 vaccine. But the balance of benefits and risks for any product can change at any time during its marketed life, for example if a serious new side effect is established.

For this reason the MHRA continually monitors the safety of all medicinal products authorised in the UK, including the COVID-19 vaccines. The process is termed pharmacovigilance and this involves:

- monitoring the use of medicines in everyday practice to identify previously unrecognised adverse effects or changes in the patterns of adverse effects
- assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use
- providing information to healthcare professionals and patients to optimise safe and effective use of medicines
- monitoring the impact of any action taken

You can read more about the MHRA's safety assessments for COVID-19 vaccines here Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)

As stated above, all medicinal products are authorised based on an assessment of the benefit/risk - that is the benefit to the patient being greater than the known risks associated with taking that product. To understand the assessment of the benefit/risk for each of the Covid-19 vaccines authorised, please refer to the Public Assessment

Reports (PARs) for each of the vaccines that we have provided links to in our previous responses to you.

Vaccine efficacy is usually measured in randomised controlled clinical trials. It is calculated by comparing the proportion of trial subjects that developed symptomatic COVID-19 in the vaccine arm with the proportion that developed symptomatic COVID-19 in the placebo arm. The calculation is made after a certain number of COVID-19 cases have occurred in the trial as a whole. This number is decided at the start of the trial. This means that a time period is not chosen.

More details on the measurement of vaccine efficacy are provided in the PARs that you have already received.

We hope this information is helpful.

If you have a query about the information provided, please reply to this email.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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:

Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre

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