FOI 22/1119 – marketing authorisations

Request
15 November 2022

1 I would like to ascertain the reasons behind this decision when based on real time data data available at the time showed that the vast majority of the population would not be at severe risk and even many of those that were at risk would not be affected by this virus in that hospitalisation/death would not occur . This was stated at the time on several news outlets by Chris Whitty and the then health secretary Matt Hancock (media proof of this is available in the public domain)
On what information and data was this decision based on (as again knowingly the data available showed that Sars cov 2 (Covid 19) had a recovery of at LEAST 99.98 % recovery rate) and was later shown in the British Medical Journal to be even lower

2 How were the Sars cov2 (covid -19) vaccines able to have an "emergency use vaccine " able to have a temporary authorisation put on them due to this disease no longer being classed as a HCID ?
based on what criteria/data ?

3 Do these vaccines STILL have a temporary authorisation ?
ARCHIVE: Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (Regulation 174)

4 When if at all will these vaccines be given a FULL marketing licence

5 The MHRA have a monitoring system in place namely the yellow card however for a few months now this has not been updated with any deaths or adverse reactions ! can you please explain why this is the case . As with any new drug the monitoring of its safety and efficacy is supposed to be continually monitored until the Expected end date is reached as with Pfizer the Primary and Study completion date is estimated to be march 31st 2023

Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California - Full Text View - ClinicalTrials.gov

MHRA RESPONSE
27 January 2023

Question 1, this is outside of our remit. You may wish to check with the Department of Health and Social Care. dhsc.publicenquiries@dhsc.gov.uk

Question 2, none of the Covid vaccines were given “emergency use authorisation”, Authorisation under Regulation 174 allowed for specific batches of vaccine to be authorised for use at the start of the vaccine rollout, ahead of the conditional marketing authorisations that were granted shortly afterwards.

Question 3/4, we have communicated to the requester previously that the vaccines have been granted marketing authorisations. As authorisation under Regulation 174 allowed for specific batches of the vaccine to be authorised for use at the start of the vaccine rollout, these authorisations have become obsolete as these batches have been used up. Batches currently in circulation are based on the marketing authorisations that have been granted.

Question 5, we work closely with the UKHSA to ensure that details on how to report suspected side effects are in included in training material for vaccinators and this is also included within the Patient Information Leaflets (PIL) which encourage reporting directly to the Yellow Card scheme.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

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

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