Medicines & Healthcare products
Regulatory Agency

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[redacted]

20 November 2023

Dear [redacted]

FOI 23/817

Thank you for your request for information dated 21 October 2023.

Where you asked:

“Many thanks for your fulsome response.

I think it is fair to say that the shift from a 'watchdog' to an 'enabler' is an initiative driven by the MHRA, and that that decision was discussed and agreed by all involved.

It also seems clear that the catalyst for this change was the covid-19 issue. What I couldn't find amongst the documents you provided, however, was the data, or the risk benefit analysis in relation to covid-19 vaccines that provides the scientific and medical basis, and justification, for that decision. As requested in my original request, I would be grateful if you could please provide that also.

The information that was provided was very useful, though it does prompt further questions.

Under the precautionary principle, things are considered unsafe until they are shown to be safe. As an enabler, the focus is on rolling-out products quickly to realise the benefits as soon as possible. Inherent in this is the assumption that the benefits outweigh the potential dis-benefits.

If this approach is taken, then it is essential that real-world data, post roll-out, is gathered and thoroughly interrogated as it comes in, and the suitability, or not, of continuing the roll-out reappraised in light of that new information. Could you please provide the data and assessments that demonstrate that this was done and that the new data supported the view that the continued use of the covid-19 vaccinations was appropriate.

Also, I seem to recall the emergency use authorisations for the covid-19 vaccines was granted on the basis that they would reduce the spread of covid-19 by stopping vaccinated individuals getting covid-19 and thereby preventing the spread. It became evident fairly early on in the vaccine roll-out that the vaccinations did not stop people getting covid-19 and did not stop those with covid-19 from spreading it. The only claim that persisted was that if you were vaccinated and you did get covid-19, then your symptoms would be milder than if you had not been vaccinated, though I have seen no data to support such a claim. If you have those data I would be interested to see them. That aside, can you please explain why covid vaccines were allowed to continue to be used under the emergency use authorisation when they demonstrably failed to deliver the outcome for which the authorisation was granted.

Many thanks again for your response and I look forward to hearing from you soon."

From the above, we identified the following questions (1-3) and you will find our responses below.

1. *"Inherent in this is the assumption that the benefits outweigh the potential dis-benefits. If this approach is taken, then it is essential that real-world data, post roll-out, is gathered and thoroughly interrogated as it comes in, and the suitability, or not, of continuing the roll-out reappraised in light of that new information. Could you please provide the data and assessments that demonstrate that this was done and that the new data supported the view that the continued use of the covid-19 vaccinations was appropriate."*

Our response*:*

While the MHRA as the UK regulator for medicinal products is responsible for ensuring that the benefits of all authorised COVID-19 vaccines continue to outweigh the known risks, the MHRA is not responsible for decisions on vaccination policy in the UK. The Joint Committee on Vaccination and Immunisation is responsible for advising the UK Government on matters such as vaccine roll-out.

The MHRA's position is that the benefits of the COVID-19 vaccines authorised in the UK continue to outweigh the known risks for the majority of people. However, as this position is based on the cumulative evaluation of safety and effectiveness since first authorisation, rather than a single report, the information requested is considered to be exempt under section 12 of the FOI Act. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

This information is held in several different repositories within MHRA which would require separate searches to identify documents of potential interest, followed by review of retrieved documents to determine whether they contain relevant information.

Based on the breadth of information requested, identification of all information that may be relevant to your request would involve the use of a Discovery Search Tool. Based on experience in using this tool to perform Agency-wide searches for documents, the time taken

to set up and refine the search criteria then extract and review the results to identify relevant records would take in excess of 24 hours.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request, for example, to one vaccine and a specific type of information, subset of data or safety topic. However please note that other exemptions may affect release of the requested data.

You can find information on the MHRA's safety assessment of the COVID-19 vaccines in the Summary of coronavirus Yellow Card reporting.

> 2. "Also, I seem to recall the emergency use authorisations for the covid-19 vaccines was granted on the basis that they would reduce the spread of covid-19 by stopping vaccinated individuals getting covid-19 and thereby preventing the spread. It became evident fairly early on in the vaccine roll-out that the vaccinations did not stop people getting covid-19 and did not stop those with covid-19 from spreading it. The only claim that persisted was that if you were vaccinated and you did get covid-19, then your symptoms would be milder than if you had not been vaccinated, though I have seen no data to support such a claim. If you have those data I would be interested to see them."

Our response:

The temporary authorisation of the first COVID-19 vaccines under Regulation 174, is described in the public assessment reports for each vaccine. The main clinical studies are also published in scientific journals:

Clinical Studies

Pfizer/BioNTech
https://www.nejm.org/doi/full/10.1056/nejmoa2034577 *BNT162b2*

Moderna
https://www.nejm.org/doi/full/10.1056/nejmoa2035389

AstraZeneca
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext

As described in the study publications these trials looked at the number of cases of COVID-19 in participants in vaccinated subjects compared to a placebo, the studies were not designed to measure onward transmission.

This information is generally considered to be not held. However, MHRA may hold some information based on real-world data related to milder symptoms in the those that have received COVID-19 vaccines. However, this information would be contained in a number of locations related to the different vaccines, or potentially combined, and could include information on emails. To search for this information, given that the limit has already been exceeded by question 1, means that this question is also subject to a Section 12 refusal.

Please note, in relation to publishing information related to the spread of COVID-19 UK-HSA are primarily responsible.

https://www.gov.uk/guidance/monitoring-reports-of-the-effectiveness-of-covid-19-vaccination

3. "And – *That aside, can you please explain why covid vaccines were allowed to continue to be used under the emergency use authorisation when they demonstrably failed to deliver the outcome for which the authorisation was granted."*

Our response:

The temporary authorisation of the COVID-19 vaccines under regulation 174 of Human Medicines Act 2012.
When a new medicinal product is approved, MHRA medical writers and assessors summarise the evidence that supports the quality, safety and efficacy of the product and explain how the MHRA's decision was reached in each case.

These 'public assessment reports' provide the basis for the authorisation of the COVID19 vaccines under regulation 174, explaining the quality, non-clinical, and clinical data which provided the support for positive benefit-risk decisions. They explain why approval was given and also provide sufficient technical information to allow interested members of the public to understand the evidence.

Public assessment reports (for the 174 Authorisations)

COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA)

COVID-19 Vaccine Moderna, 0.20 mg/mL dispersion for injection

COVID-19 Vaccine AstraZeneca suspension for injection (ChAdOx1-S [recombinant]

In terms of transmission we refer you to the following publication which explains, "Several studies have provided evidence that vaccines are effective at preventing infection, uninfected people cannot transmit; therefore, the vaccines are also effective at preventing transmission". Furthermore, even if reduction of transmission was subtracted entirely from the equation, the benefits in terms of prevention of illness and reduction in deaths, would be very likely to continue to support a positive benefit-risk outcome for the COVID-19 vaccines. This is supported by data from studies such as the below, and given that our ongoing review of the safety data collected through the Yellow Card scheme indicate that the majority of side effects are mild, short-lived and self-limiting.

PHE monitoring of the effectiveness of COVID-19 vaccination - GOV.UK (www.gov.uk)
COVID-19 vaccine surveillance reports (weeks 19 to 38) - GOV.UK (www.gov.uk)
Global impact of the first year of COVID-19 vaccination: a mathematical modelling study - The Lancet Infectious Diseases

We work closely with our public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects. In addition to this, the nature of Yellow Card reporting means that reported events are not always proven side effects. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated, and especially when most vaccines are being given to the most elderly people and people who have underlying illness. A full list of known risks and side effects can be found in the vaccine Patient Information Leaflet, and can be accessed from the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/.

Please note, when making requests for information it is best to separate the questions from the prose, this makes it easier for staff processing the request, and makes it less likely that questions will be mis-interpreted or missed.

We trust that you will find this information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

MHRA Customer Service Experience
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