Our ref: FOI 22/1229

Dear [redacted]

Thank you for your requests under the Freedom of Information Act, received in separate emails each dated 28 December 2022. Please accept our apologies for the delay in this response.

Each of your emails contained a series of questions, which we have listed below.

1. Does the MHRA have a Conflicts of Interest policy? Please provide a copy?
2. Please provide a simple list of all new regulations or regulatory changes which the MHRA published over the past 10 years, since (1 January 2013 – 1 January 2023)?
3. What is the MHRA's acceptable levels of injury before withdrawing authorisation to use medicine?
4. From 1 January 2021 to 1 January 2023, did the MHRA benefit from bonusses, incentives, or any increased funding linked to Pfizer's profits?
5. With regards to the Pfizer's MRNA vaccine, please provide details of how Pfizer satisfies the regulatory body (MHRA) with transparency, accountability, incident reporting or disclosure obligations?
6. https://www.legislation.gov.uk/uksi/2012/1916/regulation/75/made UK law requires licence holder to provide information relating to safety.
   6.1 Please provide the safety information from the Pfizer MNRA vaccination prior to authorisation?
   6.2 Please provide the post authorisations studies and reports from Pfizer about efficacy and safety of their MNRA vaccine?

1. During the period 1 April 2020 to 31 December 2020, the MHRA acted in an advisory role to the Vaccine Taskforce. Please provide details of advice provided to the Vaccine Taskforce during this period - any emails, recommendations, meeting minutes etc?
2. The Vaccine Taskforce signed a secret contract with Pfizer in July 2020 - excluding liability provisions to Pfizer - and on 2 December 2020 the MHRA provided "temporary emergency use authorisation" for Pfizer's MNRA vaccine. How long is a "temporary emergency use authorisation" valid for?
3. Was the authorisation from the MHRA conditional in any way, if so, kindly provide details of the conditions?
4. Before the MHRA approved Pfizer's MNRA vaccination, did the MHRA preform a risk assessment or give any consideration to the gap in recourse to compensation of patients? Please provide copies of any risk log and mitigation measures relating to the Pfizer MNRA vaccine?
5. If the MHRA did not perform a risk assessment or risk mitigation for potential injured recipients of the Pfizer MNRA vaccine, does the MHRA have any prior examples of approving medication with no consideration for potential injuries?
6. The MHRA's "Patient Safety" mantra – Please explain how the MHRA achieved its primary objective of "Putting Patients First" when the Pfizer contract provided no recourse to action for the UK public, and there are thousands of yellow card reported injuries?

1. When did the MHRA receive the first yellow card reports for Covid Injuries due to the Pfizer MNRA vaccination?

2. After reporting a serious adverse reaction on the yellow card system, the MHRA contacted patients through the yellow card process, to collect specific targeted data from individual patients who reported serious vaccine injuries. The next 6 questions relate to this specific targeted data of serious adverse effects:
   2.1 What was the purpose for collecting this specific set of vaccine injured data?
   2.2 What questions were asked to the seriously injured?
   2.3 How many individuals did you target and issued your questionnaire to? How many patients responded?
   2.4 What were the nature of injuries reported in this data set for the Pfizer MNRA vaccination?
   2.5 Did the MHRA share any of this data (personal information or anonymised) with Pfizer or any external parties?
   2.6 Did the MHRA share this set of data set about serious vaccine injuries with other government departments or Medici?
   2.7 Did the MHRA publicly release, or do you plan to publicly release anonymised patient data of serious vaccine injuries as collected under the "yellow card" covid-19 vaccine adverse events reporting scheme?

Whilst these questions were sent across three individual emails, all referenced the 'Pfizer MRNA vaccine' / 'Pfizer MRNA vaccination'. Guidance from the Information Commissioner's Office notes that:

> When a public authority is estimating whether the appropriate limit is likely to be exceeded, it can include the costs of complying with two or more requests if the conditions laid out in regulation 5 of the Fees Regulations can be satisfied. Those conditions require the requests to be:
>
> - made by one person, or by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign;
> - made for the same or similar information; and
> - received by the public authority within any period of 60 consecutive working days.

We judge that your three emails satisfy the above criteria and we have considered them as one request.

Before we address your request, we wish to confirm that there is a significant amount of information available via the sources below, which will provide information that is in scope of some of what you have requested from us:

- MHRA Public Assessment Reports for Comirnaty – provides an overview of the authorisation process including the data considered.
- The European Medicines Agency clinical repository – this provides the clinical data submitted as part of the approval process.
- Our summary of Yellow Card reporting – which discusses the safety monitoring we undertake.
- COVID-19 Vaccine reports – which contain a complete listing of all suspected adverse reactions that have been reported via the Yellow Card scheme for all COVID-19 vaccines.

We can confirm that we hold some of the information you have requested. However, our assessment of your request is that Section 12(1) of the Freedom of Information Act applies, and we cannot proceed any further. 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.

Your request is broad, and the following is just one example which demonstrates why we consider Section 12 to apply. Your request includes a question and sub-questions regarding Yellow Card reports and follow up contact with patients. While we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable. The MHRA has received over 470,000 Yellow Card reports associated with a COVID-19 vaccine. An individual would need to manually open each Yellow Card report to check whether a request for further information was sent. Checking a single Yellow Card report for evidence of follow up would take a minimum of 45 seconds and in some instances longer. This would equate to 5875 hours for this aspect of your request alone, not including manually reviewing to determine if the request for information had been answered.

Based on the large amount of information already available in the public domain (which we have linked to above) and the wide scope of the current request, it is not possible for us to suggest how to refine your request to bring it within the Section 12 cost exemption.

We apologise once more for the delay in response.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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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Communications and engagement
Medicines and Healthcare products Regulatory Agency
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