Medicines & Healthcare products
Regulatory Agency

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[redacted]

07th March 2024

FOI 24/132 (questions 1-12) & 24/133 (question 13)

Dear [redacted],

Thank you for your Freedom of Information requests, both dated 8 February 2024, where you requested information on COVID-19 Vaccinations. There are provisions under the FOIA that allow for the aggregation of requests of the same or similar information from a requestor within a 60-day time period. This means that the time needed to retrieve information for the requests can be added together. As such your requests have been aggregated; the time needed for any further requests on the same or similar subjects made within a 60 day period may also be aggregated.

A single combined response has been provided to FOI 24/132 and FOI 24/133 below.

1. *Is it true that Moderna and Pfizer J&J and other manufacturers of covid 19 Jabs are investing and creating a MRNA cell therapy products and is MHRA investing money to theses products is so please state how much and what information on this technology*

The MHRA do not hold this information.

2. *What are the Difference of the COVID-19 Jabs/Gene therapies products make them different to what MRNA Cell/Gene Therapy products*

The MHRA hold this information as the definitions of a vaccine and gene therapy is detailed in the Human Medicine Regulations 2012. MRNA cancer immunotherapies are commonly known as cancer vaccines by scientists and clinicians in the clinical development of these products, but this term contradicts the UK regulatory terminology. Traditionally, a vaccine prevents an infectious disease. The definition of a vaccine as per the Human Medicines regulations 2012 state:

“vaccine” means an antigenic substance which consists wholly or partly of—

(a) any micro-organisms, viruses or other organisms in any state;
(b) any toxins of microbial origin which have been detoxified (toxoids); or
(c) any extracts or derivatives of any micro-organisms or of any viruses, being substances which, when administered to human beings, are used for the **prevention** of specific diseases;

Due to part (c) cancer mRNA immunotherapies cannot be vaccines. Instead, both UK and EU regulators use the term 'immunotherapy' to describe products that illicit immune responses to target tumours. The regulations classify mRNA-based cancer therapies as advanced therapy medicinal products (ATMPs), specifically, gene therapy medicinal products.

3. *What information does MHRA holds to Covid19 Jabs Adverse Reactions on acceleration cancer coursed from the Jabs and manufacturers Acknowledgement of this as Potential side effects other words the wouldn't be need for A MRNA Cell/Gene therapy products for cancer if the manufacturers didn't no if could be Potential Adverse Reactions from Covid19 Jabs can you see this doesn't look good creating problem find and sell the solutions this seems to be*

The MHRA holds information on suspected adverse reactions however we do not determine causality of individual reports. The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products. The scheme relies on voluntary reporting from the public as well as from healthcare professionals. There are also legal requirements for manufacturers to report problems with their healthcare products to the MHRA.

This information however is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available. The MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here on the Yellow Card website. You will be able to access a complete listing of all suspected adverse drug reactions (ADRs) that have been reported to the MHRA via the Yellow Card scheme for all of the COVID-19 vaccines. You will be able to find information here about the number of reports of suspected cancer on the reaction profile page for each vaccine.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction. This information does not present a complete overview of the potential side effects associated with specific medicines. A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and

the recipient information here. Conclusions on the safety and risks of medicines cannot be made on the data shown in the Interactive Drug Analysis Profile alone.

4. *with the Covid-19 Jabs knowledge now to caused Myocarditis Strokes Heart attack Deaths does MHRA possibly admit they a chance small or large that Covid19 Jabs from all manufacturers could cause certain Cancer types and maby Accelerate Cancer cells do you agree the possibilities of cancer forming after Covid19 jab we know spike protine don't stay in Deltoid can be found all around the body and causes Vaids*

Opinions or views are outside of the scope of FOIA which grant access to recorded information held at the time of the request. As you have asked for opinions this question is not valid under FOIA. However, under section 16, duty to assist, I can confirm that currently no cancer events are recognised as a side effect of any of the COVID-19 vaccines. The MHRA will continue to review emerging safety information related to COVID-19 vaccines and will take regulatory action to minimise and communicate any new risk to healthcare professionals and the public.

5. *does MHRA going admit that Government stance on safe and effective is a lie stopping transmission*
   Pfizer admitted in European Parliament that they never tested stopping transmission they never had the time thanks to EMP Rob Roos members questions do you stand by this as well

Opinions or views are outside of the scope of the FOI Act which grants access to recorded information held at the time of the request. As you have asked for opinions this question is not valid under FOIA.

To assist, we can advise that the MHRA's position on the COVID-19 vaccines authorised in the UK is that the benefits of vaccination outweigh the known risks for the majority of people.

6. *from 2020 to 2024 how many yellow card and confirmed injuries and deaths be cause by all Covid-19 Jabs and in age groups please*

As stated above, the MHRA does not determine causality of individual reports and therefore does not hold information on the number of patients that have a COVID-19 vaccine listed as a cause of death, as this falls outside of our remit. If you are interested in this information, I would advise you to contact the Office for National Statistics (ONS): Contact us - Office for National Statistics (ons.gov.uk).

The MHRA holds information on suspected adverse drug reaction reports for the COVID-19 vaccines however, as explained in FOI 23/801 and above on point 3 this information is exempt under section 21 of the FOIA as suspected adverse drug reaction reports for the COVID-19 vaccines can be found on our website. The filters on the right-hand side of the page allow the reports to be filtered by age group.

Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.

7. *can you compare all injuries and deaths in number from all Covid19 Jabs from 2020 to 2024 compered with all other type of vaccines Injuries and deaths excluding/No Covid19 jabs that including with suspected courses and confirmed courses in number*

This question falls outside the scope of the FOI Act as it does not ask for recorded information already held by the public authority. As explained in FOI 23/801, it is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

8. *did MHRA knew about FDA slide sheet of adverse Reactions on 22 2020 did this prompt MHRA to react with need for a Contract for AI Adverse Reactions reporting System quotes The MHRA urgently seeks an Artificial Intelligence (AI) software tool to process the expected high volume of Covid-19 vaccine Adverse Drug Reaction (ADRs) and ensure that no details from the ADRs' reaction text are missed.506291-2020*

We are unsure about what the FDA slide sheet you are referring to is, in order to proceed with this as a request you would need to provide further information on this and clearly describe what recorded information you are seeking. The response to your previous FOI 23/801 details why the MHRA awarded the AI contract in order to support our existing systems.

9. *following up on Question 8 why did MHRA think of The Expected High Volumes of Covid-19 vaccine Adverse Drug Reaction did MHRA bad feeling they wasn't going to be safe or was because pharmaceutical lack of trials and unpromising safty data which Pfizer and FDA tried to Hide for 75 years until court stop them from hiding the data was released to public*

This question again falls outside the scope of the FOI Act as it does not ask for recorded information already held by the public authority. However please review our response on the expected volume of reports in our response to your previous FOI 23/801.

10. *out all Adverse Reactions in Covid19 Vaccines with Still Births and miscarriage why was it recommended to pregnant women around the world MHRA has working relationships with EMA FDA and pharmaceutical companies the MHRA post Regulate these products to make sure its safe to*

public Use but MHRA admit it takes money from Pharmaceutical companies to Regulate they products does this not look like a conflict of interest

The requested information 'why was is recommended to pregnant women around the world' is not held. The MHRA is not responsible for making recommendations on vaccination policy, such as whether pregnant women should receive COVID-19 vaccines. In the UK, the Joint Committee on Vaccination and Immunisation (JCVI) advise the Government on which groups of patients should receive vaccinations.

In response to the question around conflict of interest, this is not considered to be a valid request for information under the FOI Act. However, you may be interested to know that the fees that we charge for our services reflect the cost of providing that service and these are set in legislation, following Parliamentary scrutiny. This cost-recovery approach, which is common to the majority of medicines regulators, means that those who wish to market their products in the UK bear the cost of having those products assessed, as well as ensuring the MHRA does not profit from fees or make a loss which must then be subsidised by the Department of Health and Social Care or wider Government. Further detail about our funding is available in our Annual Report and Accounts on pages 15 and 50 and from page 118 onwards in the financial statements.

11. *so in previous FOI MHRA say different definitions of what GENE Therapy products are and when we was in European Union 2011 Well we are not part of EU but you still follow alot what EMA says in pervious reply and like laboratory MHRA think it time think for it self's and not listen to what other agency are saying like FDA is captured and sponsored by big pharm I personally think MHRA should be more controlled and independently Regulate it self no money given by big pharm or buy Foundation like gates Foundation which could be considered conflict of interests*

This question falls outside the scope of the FOI Act as it does not ask for recorded information already held by the public authority Please see the advice at the end of this letter.

12. *what doe it take to take products withdrawn from market if the product does not benefit the people out ways the risk what number of population*
    1-800
    1-10.000
    1-100.000

As explained in FOI 23/852 and reiterated in the Internal Review of FOI 23/852, the MHRA do not hold the information requested as the MHRA does not have a threshold for the number of suspected Adverse Drug Reaction (ADR) reports required to take specific regulatory actions, such as revoking a marketing authorisation. Please review those responses for further detail on this topic.

13. *When did MHRA receive 90-day post marketing dossiers of data for all vaccine manufactures? How was it communicated? Where there any calls or emails concerning the large numbers of deaths in those files?*

We are not clear what information corresponds to your description, "*90-day post marketing dossiers of data"*. If you wish to provide further details, we will consider if this can be taken forward as a new request.

Finally, I thought it may be useful to include links to some guidance produced by the Information Commissioner's Office (ICO) on writing effective FOIs. We particularly draw your attention to the ICO's 'top tips' for making a clear request.

https://ico.org.uk/for-the-public/official-information/

Top tips

To make information requests as efficiently and effectively as possible, we suggest you take this approach:

i. ***Search first.*** *Public authorities publish a great deal of information. You may find what you're looking for by searching online or looking at the website's sitemap. If the information is already in the public domain, it may be quicker to find it than ask for it.*
ii. ***Keep it clear.*** *Make your request as simple and straightforward as possible. Use simple language. Numbered lists or bullet-points might help you to structure your request. In general, try to make it as easy as possible for the public authority to understand what you want to receive.*
iii. ***Be nice.*** *Even if you're dissatisfied with the organisation, try to put that to one side and focus on the information you want to receive. If possible, keep your information request separate from any ongoing email threads or complaints about wider issues.*
iv. ***Read it twice.*** *Before you send a request, take another look at it to make sure it's clear and easy to follow. If you're unsure, you could seek a second opinion from someone you know. They might spot something confusing that you can fix before you send the request. If the public authority has to ask you to clarify your request, it will take longer for you to receive the information you want.*

Protect public money

Gaining access to public information is your right and public bodies must respect that.

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However, requests do cost public bodies time and money to respond to. This is public money and we need to make sure it's spent responsibly.

It is important that you don't submit frivolous or trivial requests.

You should not make requests for the same information more than once, unless the information has changed a lot.

You should not make requests as a way of 'punishing' a public body if you think they have done something wrong. If you do any of the above, the public body could consider your request vexatious and refuse to action it.

We hope you find this response and the advice provided useful. 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

Please remember to quote the reference number above in any future communications.

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

Information Commissioner's Office
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Water Lane
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