Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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**22nd March 2024**

Dear [redacted]

**FOI 24/182 and FOI 24/183**

Thank you for your emails dated 23rd February 2024, where you requested information related to issues with data used in post authorisation safety studies.

Specifically you sent two emails, the bodies of which are copied below:

FOI 24/182

*Pfizer's Covid vaccine Post-Authorisation Safety Study Interim Reports refer to "CPRD server capacity issues" and "a quality issue with the CPRD data availability".*
*Please can you*
*a) send me any MHRA internal document(s) which describe in more detail the nature of these issues, the steps being taken to resolve them and the timescales for resolution.*
*b) confirm whether or not either or both of those issues are now resolved.*

FOI 24/183

*Since the Covid vaccines were first authorised, there have been reports of individuals' Covid vaccination records being incorrect - including being recorded as unvaccinated when they had been vaccinated; and vice versa.*

*Please can you send me:*
*a) the minutes of any meetings with NHS about the issue*
*b) the minutes of any meetings about the issue involving MHRA CEO (Dame June Raine)*
*c) copies of any MHRA assessments of the impact of the issue on Covid vaccine Post-Authorisation Safety Studies*

Given the simultaneous timing of these two requests, we have aggregated them under Section 12(4d) of the FOI Act (with sections 5(1) and (2) of the Fees Regulations). This exemption applies when one or more requests is made for related information within a period of 60 consecutive working days. In these cases, the time needed for retrieval for each of the requests may be

aggregated, and if this exceeds 24 working hours then section 12 applies. The time required to identify potentially relevant documents and search them to retrieve any information meeting the specifics of your request would be in excess of 24 hours, therefore provision of this information is 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.

In order to conduct a full search to identify all and any documents including information relevant to this request key word searches are required. The reason that has led to us reaching this conclusion is the lack of specificity in your request and the challenges in developing an appropriate key word search strategy. The term 'documents' can refer to any number of types of information including meeting minutes, briefing papers, or correspondence. Meeting minutes could be stored as documents or, more likely, within emails. Similarly, assessments could be included in multiple types of documents meaning that a broad search would be required. Further, in order to ensure that any relevant information was retrieved very general key terms including those such as "incorrect", "missing", "misclassified", "quality", and "server", for example, would be required. These issues would result in a very large number of items being returned with no way to easily isolate potentially exempt information because it would be extensively scattered throughout many multiple items. We note that this was an issue that arose in respect of a previous request requiring keyword searches, FOI 23/1002.

We can however provide some further advice and assistance. We will first give some explanation with regards to the points you mention in 24/183 and then provide a suggestion about how you may proceed with a narrowed request in respect of the information sought in 24/182.

In considering the first two parts of 24/183, staff members involved in discussions with branches of the NHS on implementation of the COVID-19 vaccination record data capture systems were consulted to advise if they can recall any meetings covering the topic of incorrect records. Similarly, in considering the third part of the request, relevant staff members involved in the regulatory assessment of post-authorisation safety studies were asked if they were aware of any such assessments. I can confirm that in that consultation no relevant meetings or documents were identified.

In order to consider the potential impact of errors in the data regarding vaccination status or details on the interpretation of the results from post authorisation safety studies two potential issues can be considered. Firstly, that data are incorrectly recorded at the point of care or, secondly, that they are corrupted between their initial capture and subsequent analysis. With regards to the first, we do not understand there to be an issue of the type or magnitude that could impact on the interpretation of post authorisation studies. While small numbers of individual patient records may be incorrect, this will be a very small proportion of records and there is no reason to believe that the occurrence or nature of this is in any way associated with patient outcomes meaning it will not affect the results of analyses based on them. If we consider the second, the majority of studies conducted in the UK on vaccine safety used data directly from the National Immunisation Management System minimising the potential for post-capture data corruption.

While conducting our estimate of time needed to respond to these requests, we have identified several documents that if you wish to proceed with a narrowed request could be retrieved and

considered for disclosure. These are the distributed CPRD bulletins related to the data quality issue and a copy of the CPRD internal Wiki Page about the subject up to 25th May 2023.

We can also confirm that both issues mentioned in 24/182 are now resolved.

Yours sincerely,

FOI Team,
Safety and Surveillance Group