Medicines & Healthcare products Regulatory Agency

South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

09 March 2023

Dear [redacted]

Internal review: FOI 22/1157

We are writing in response to your request for a review of our reply to your Freedom of Information (FOI) request (**22/1157**).

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA).

In your request for this internal review, you stated that you were dissatisfied with the original response on the basis outlined below:

> "My request was specifically in relation to the MHRA's decision and not the EMA's. So the information provided in your response does not answer my original request.
>
> I am therefore asking the MHRA to review its position in relation to that request and provide the data directly, or accurately cite individual studies and individual specific databases for each of the three Comirnaty formulations, for the age groups I requested.
>
> For clarity, here is my original request:
>
> Under the 'Freedom of Information Act 2000' and for the following Comirnaty products:
>
> - Comirnaty 30 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0002);
> - Comirnaty 30 micrograms/dose Dispersion for Injection (PLGB 53632/0004); and
> - Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0006).
>
> I request disclosure of:

a) Any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021 and which supported the MHRA's decision to change the status from Conditional Marketing Authorisation to full Marketing Authorisation?

b) In addition to information relating to adults, please provide any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021, for children aged 5-11 and children aged 12-18, which supported the MHRA's decision to change the status from Conditional Marketing Authorisation to full Marketing Authorisation and

c) In particular, any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021 which confirms each product's benefit-risk balance is positive?"

Our original reply to your request (included at Annex A), dated 07 December 2022, was provided in good faith and directed you to the European Medicines Agency repository. However, the response did not confirm whether we were applying any exemptions, nor did it explicitly state whether what you had requested could all be located within the repository. In this review we intend to address this and wish to apologise that our original reply did not do so.

Whilst the original response did not refer to Section 21 (Information reasonably accessible to you by other means), the European Medicines Agency repository does contain clinical data, and the dossier which was submitted to us is the same as that reviewed by the EMA.

This point notwithstanding, if we were to fully address your request under the provisions of the FOIA, we judge that there are two ways we could do this:

1) Release all data received by us since January 2021, in scope of your request, concerning the three Marketing Authorisations you have asked about.
   OR,
2) Review all data received by us since January 2021, in scope of your request, concerning the three Marketing Authorisations you have asked about, and verify that the exact same data is published in the EMA Repository.

For us to take either 1) or 2) forward would be a significant undertaking. Therefore, we are overturning the original position and now consider it necessary to apply Section 14 to your request, due to the considerable burden that would be placed on the MHRA were we to take either of the approaches described above. The Information Commissioner's Office (ICO) guidance on Section 14 includes the following:

> *"A single request taken in isolation, for example the first and only request received from an individual, may be vexatious solely on the grounds of burden. That is, where complying with the request would place a grossly*

oppressive burden on your resources which outweighs any value or serious purpose the request may have".

Downloading the dossier of each vaccine is expected to be a relatively straightforward task, however, the time required to re-read through the dossiers and to consider and make redactions we expect would take many weeks, if not months to complete.

We judge that to meet the request under point 1) above, our staff:

- Would need to re-read the dossier in full for each of the three vaccines, in order to identify where redactions need to be made.
- Extract the dossiers - as mentioned above, this is perceived to be relatively straight-forward task but is not time negative.
- As per best practice, would need to solicit views from third parties, and consequently this step requires the dedication of further resource to consider any proposals against transparency guidelines and FOI exemption criteria.
- The material to be redacted is dispersed unevenly throughout the dossier, for example, personal information is present in many documents in terms of authors (these can be located in headers, footers, or in-text mentions), clinical data also needs to be carefully considered to establish if any identifiers or pseudo-identifiers of trial participants or patients are present. An extremely careful approach needs to be taken to ensure no names of research organisation staff are included in for example in the non-clinical portion of the dossier to maintain confidentiality. The quality parts of the dossier also include a mix of information that can be released and that which cannot, for example the headings in a table of parameters could be releasable, but the acceptance criteria are expected to be commercially sensitive. Some proposals for redactions would require input from different assessment teams to understand if the claims made by the authorisation holders are valid for example, in instances where certain information is claimed to be commercially sensitive.
- Would need to apply the redactions which requires use of a manual mark-up tool in Adobe. We do not use an automated tool due to a risk of accidental disclosure, for example, misspelled words could potentially be overlooked by automated tools.
- Once redactions are made, a further step is taken to make the redactions irreversible, this step has to be completed individually for each document that requires redaction, we expect almost all documents to require some form of redaction e.g., due to the presence of personal information.

If we instead conducted a comparison exercise (option 2)) above) then we judge that any time saved from redaction activities would instead be concentrated on reviewing the data within the repository, noting the data on the EMA Repository will have been anonymised / obscured according to the anonymisation report, and this will complicate the comparison process.

From a transparency standpoint, the level of data available in the EPARs and the EMA clinical data repository, coupled with data that are due for future publication, somewhat negates the value of your request, and therefore, in our opinion mounting an anonymisation / redaction exercise to meet your request would not be conducive

to better serving the public interest, rather than for example, time focused on other regulatory activities.

We also feel it is pertinent to mention that the MHRA operates licensing procedures in conjunction with the advice and decisions of independent panels (expert groups). The membership lists of these groups are available on our website (Membership - Commission on Human Medicines - GOV.UK (www.gov.uk)), and to briefly describe the individuals involved in these groups they include a range of experts from numerous UK academic and medical institutions such as professors, researchers and consultants.

Conclusion

We apologise that our original response did not confirm whether we were releasing or withholding the information you have requested. We hope that this reply explains the data that is published and available to you and why we are not able to comply fully with your request.

If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with your request and subsequent internal review. The ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Annex A – Original Response

FOI 22/1157

[redacted]

Thank you for your email.
The change from CMA to MA was done following the second annual renewal of Comirnaty, where no new data emerged that would alter the benefit/risk for these products. The CHMP concluded that the clinical safety profile, as well as the efficacy of this product, may now be considered comprehensively characterised, in the sense of the conditional marketing authorisation (CMA) legislation and the CMA converted to a full MA.
Further information is available from the EMA, see the link below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

With regards to data submitted since January 2021 for Comirnaty, these are available through the EMA repository, linked below:
https://clinicaldata.ema.europa.eu/web/cdp
If you have a query about the information provided, please reply to this email.
If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre
Communications and engagement team
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