Medicines & Healthcare products
Regulatory Agency

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

[redacted]

26 August 2023

FOI 23/432

Dear [redacted]

I am writing in response to your information request FOI 23/432 to the MHRA, which was received on 10 June 2023.

Your request was as follows:

> *Dear Medicines and Healthcare Products Regulatory Agency,*
>
> *On 26 May 2023, SKYCovion, a COVID-19 vaccine developed by SK Chemicals, was authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). This authorisation was based on advice received from the independent Commission on Human Medicines (CHM).*
>
> *I would be grateful if you could provide copies of the communications/documents/evidence considered as the basis for authorising SKYCovion.*
>
> *1. Please provide the request sent to the CHM for advice on the safety, quality and efficacy of SKYCovion*
>
> *2. Please provide the advice given to the MHRA by the CHM on the safety, quality and efficacy of SKYCovion*
>
> *3. Please provide any advice received from the CHM on the impact of any safety issues on the balance of risks and benefits of SKYCovion*
>
> *4. Please provide evidence of correlates of protection underpinning the decision to infer efficacy from immunobridging*

5. Please provide any representations, reports or other evidence, other than from the CHM, considered by the MHRA in support of the authorisation of SKYCovion in respect of:

a. the quality, safety and efficacy of SKYCovion

b. the balance of benefit and risks

c. measures to minimise risks, and optimise the benefit-risk balance, such as any new precautions or restrictions on use

d. communications to health professionals and the public.

e. measures to monitor impact/effectiveness of any additional risk minimisation.

6. What obligations have been defined in respect of the provision of further evidence?

7. Please provide documentary evidence of the MHRA's consideration of the rationale for authorising a vaccine about which:

a. Efficacy inferred by comparison of immune response with another vaccine rather than in a clinical trial

b. Interaction studies had not been conducted

c. Genotoxicity and carcinogenicity studies were not performed

d. There is no experience with use in pregnant women from clinical trials

8. Please provide the risk management plan for SKYCovion

*In case you feel the scale of the evidence requested above qualifies for a Section 12 exemption, please address the information in the numbered order *as far as practicable*. Where information cannot be provided due to the scale of effort, please explain the issue.*

I apologise for the delay in responding to your request.

I mentioned in our Zoom call that I had determined that this request covered a large amount of information and my view at that time was this could be too great to deal with under FOI. It is with regret that I now write to inform you that, on this occasion, the detailed assessment of your request has determined that the scope and breadth of the information you have requested is so large that compliance with this request would create a ‘disproportionate burden’. However, I have worked this week with colleagues to provide you with advice and assistance about the information you have asked for, and I have included below advice on how you may access further descriptions of what a ‘regulatory dossier’ contains, and included several suggestions that I hope will help you proceed with a request for a smaller amount of information.

To explain, in cases such as this, a public authority may apply section 14(1) to the request, as the request falls to be termed ‘vexatious’ under FOIA. I do stress that this is solely on the basis of the burden that would be created by compliance, due to the

voluminous amount of information that would need to be retrieved and then reviewed in detail, in order to comply with your request.

The ICO's guidance and the Information Tribunal have both considered that this may apply even when there is a serious purpose to the request and there may be a public interest in disclosure. The ICO's guidance[1] advises that *"…there can, occasionally, be situations where a single request taken in isolation, imposes a "grossly oppressive burden. This is due to the breadth of information sought that it is vexatious when weighed against its value or purpose.""*

This cites the First Tier Tribunal, *Independent Police Complaints Commissioner vs The Information Commissioner* (EA/2011/0222, 29 March 2012)[2] where the Tribunal found that:

> *"A request may be so grossly oppressive in terms of the resources and time demanded by compliance as to be vexatious, regardless of the intentions or bona fides of the requester." (paragraph 15).*

In *Cabinet Office vs Information Commissioner and Ashton* [2018] UKUT 208 (AAC)[3] the Upper Tribunal agreed that even when there may be a public interest in the information, the burden of compliance may still be so great that the request would fall to be considered vexatious:

> *"In some cases, the burden of complying with the request will be sufficient, in itself, to justify characterising that request as vexatious, and such a conclusion is not precluded if there is a clear public interest in the information requested. Rather, the public interest in the subject matter of a request is a consideration that itself needs to be balanced against the resource implications of the request, and any other relevant factors, in a holistic determination of whether a request is vexatious."*

The guidance above[4] is particularly relevant to your request. My view is also informed in this case by the same ICO guidance which additionally explains that:

---

[1] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-consider-burden-motive-and-harassment/#burden

[2] https://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i725/20120329%20Decision%20EA20110222.pdf

[3] https://assets.publishing.service.gov.uk/media/5b57139a40f0b6339963e8cf/GIA_2782_2017-00.pdf

[4] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-deal-with-a-single-burdensome-request/

> *You cannot claim section 12 for the cost and effort associated with considering exemptions or redacting exempt information.*
>
> *Nonetheless, you may apply section 14(1) where you can make a case that the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on your organisation.*[5]

And:

> *15. The Commissioner's guidance on section 14 states that there is a high threshold for refusing a request on such grounds. It says that a public authority is most likely to have a viable case where:*
>
> *• the requester has asked for a substantial volume of information; and*
>
> *• the authority has real concerns about potentially exempt information, which it will be able to substantiate if asked to do so by the Commissioner; and*
>
> *• any potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.*[6]

I will explain how this applies here in some detail below. Most importantly, in the final section, I will also provide further advice and assistance as to how you could proceed with a significantly narrowed request for information relating to the SKYCovion authorisation.

The scope of the requested information

Questions 1, 2, 3, 7 and 8, all concern the MHRA Assessment report provided to the CHM, the CHM advice provided to the MHRA, and the Rick Management Plan. These documents themselves amount to 400-500 pages, and all contain information which would need to be reviewed to determined if exemptions under sections 40, 41, 43 and 22 of the FOIA apply. This is because some parts of this information will be reproduced in the MHRA's intended publication of the Public Assessment Report (PAR) for SKYCovion, and information which is not to be included in the PAR may be considered to be exempt from disclosure at this time. Each document would need to be reviewed in detail to determine whether an exemption applies and if so, which exemption applies to which part. To inform section 22, this work would need to be undertaken with the involvement of the colleague who is presently preparing the PAR itself for publication.

---

[5] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-deal-with-a-single-burdensome-request/

[6] https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4025038/ic-197426-f8v9.pdf

Medicines & Healthcare products Regulatory Agency

We discussed this request in our discussion on Zoom on Thursday 10 August. PARs are published under The Human Medicines Regulations 2012, and section 64 sets out the duties of the MHRA in this regard:

> **Duties of licensing authority in connection with determination**
>
> (6) The licensing authority must—
>
> (b)make the assessment report publicly available (with the omission of information of a commercially confidential nature) as soon as is reasonably practicable after it has been prepared or revised; and
>
> (c)include in the assessment report a summary, written in a manner that is understandable to the public, that contains, in particular, a section relating to the conditions of use of the medicinal product.

I also mentioned that the MHRA Public Assessment Reports (PARs) are published and edited in accordance with a specific EC Directive, 2004/27/EC: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0034:0057:EN:PDF

When we are considering the inclusion of information in the PAR, or whether exemptions apply to information relating to vaccine applications and authorisations, we routinely follow the established principles and guidance set out in the EMA/HMA transparency document:

https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

At this time, the MHRA are working on the PAR for SKYCovion in line with this guidance and this is not yet completed. As I explained, the PAR will draw on the assessment report provided by the MHRA to the CHM (question 1 of your request) and the advice provided by the CHM to the MHRA (question 2 of your request), and some parts may be reproduced in the published report. Section 22(1) (information intended for future publication) would therefore apply to those parts of the MHRA assessment report and CHM advice which will be included in the PAR.

Once any information to be included in the PAR has been identified, the other information in these documents – those parts of the MHRA assessment report and the CHM's advice which are not to be included in the PAR – and the Risk Management Plan will need to be reviewed to determine whether they may be disclosed or whether an exemption may apply.

We would need to conduct further searches and retrieval to determine what information may be held for questions 4, 5 and 6. For question 4, there is discussion of these subjects in the MHRA assessment report; this report is the "request" put through to the CHM to seek their advice. However, without further specification in your request of what information could be considered "evidence", this could apply to

any relevant information and data which may have been provided to the MHRA in the company's Marketing Authorisation Application.

This information – which is held in the Regulatory Dossier – is also particularly relevant to question 5, where you asked for *"any representations, reports or other evidence, other than from the CHM, considered by the MHRA in support of the authorisation of SKYCovion"*. The Regulatory Dossier contains all the information provided to the MHRA by the company applying for the authorisation. This was a full application for license, so the dossier will contain a large amount of information provided to the MHRA for their consideration.

All of the information contained within the dossier falls within the description of *"any representations, reports or other evidence, other than from the CHM, considered by the MHRA in support of the authorisation of SKYCovion"*. To meet this part of your request alone, we would need to read the dossier in full in order to identify where exemptions may apply. As per best practice and the FOI Code of Practice, we would need to solicit views from third parties on disclosure in a formal consultation process.

A key issue for the time needed is that exempt material is dispersed unevenly throughout the dossier. It is particularly important to ensure all personal information is identified and correctly withheld under section 40 of the FOIA. Different types of personal information are present in many documents in terms of authors (these can be located in headers, footers, or in-text mentions), and clinical data also needs to be carefully considered to establish if any identifiers or pseudo-identifiers of trial participants or patients are present, as these may not be provided to us in an anonymised form. An extremely careful approach needs to be taken to ensure no names of research organisation staff are included for example in the non-clinical portion of the dossier due to a risk from animal rights advocates.

The quality parts of the dossier also include a mix of information that can be released and that which may be exempt; for example, the headings in a table of parameters could be disclosable, but the acceptance criteria are expected to be commercially sensitive in accordance with the EMA/HMA (please see further details below). Some proposals for redactions will require input from different assessment teams and to consider the views put forward the third parties, for example, in instances where certain information may be commercially sensitive.

Finally, we would need to go through a process for all information for disclosure to apply 'redactions' to any information withheld. This requires use of a manual mark-up tool; we do not use an automated tool due to a risk of accidental disclosure if, for example, misspelled words or names were 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.

For a large volume of material, this last step is itself a time-consuming process, as we expect almost all documents to require some form of redaction, for example, due to the presence of personal information.

The balance of the public interest, value and serious purpose of the request versus the burden of compliance

We appreciate that there is a strong public interest in COVID-19 vaccines, however, we do not feel that the public interest outweighs the resource burden required to meet your request. In terms of transparency, the Agency already has a duty to publish the Public Assessment Reports, which will include data integral to the benefit risk of the vaccines at the time of approval, especially the clinical safety and efficacy data. In addition to this, our view is that the data included in the Summary of Product Characteristics (SmPCs) and other documentation such as that related to pharmacovigilance also addresses the public interest in disclosure here.

In our recent Zoom call, we discussed that a request for a large amount of information, all of which would need careful review and consultation in order to identify precisely where exemptions apply and particularly to remove all personal information may lead to a refusal of the request. On the basis of the explanation above, the time needed to review the full range of highly technical information across all the questions you have asked in this request would, in this case, create a disproportionate burden, and it is for this reason that section 14(1) applies.

Advice and assistance

The remainder of this letter will provide further advice on how you may narrow a new request.

I am providing here a description of how the Regulatory dossier for a vaccine will be structured. I hope that this will provide some further explanation which is useful for you in seeking to refine a request.

Description of the dossier

The regulatory dossiers of vaccines and medicines are organised in a modular structure: modules 1-5, a summary of each module is described on page 8 of the following document, '*Notice to Applicants*':

https://health.ec.europa.eu/system/files/2016-11/ctd_05-2008_en_0.pdf

This is also shown in diagrammatic form on page 10. You can use this structure to identify types of the individual documents or studies within a regulatory dossier that you may be most interested in.

To indicate the types of information that may be disclosable, I mentioned above that we routinely follow the guidance set out in the EMA/HMA transparency document:

Medicines & Healthcare products Regulatory Agency

https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

This document itemises the dossier structure, and marks information into three categories, that which is commercially confidential, can be released, or signals where exceptions / case-by-case basis approaches should be utilised. Importantly, the classifications assigned to the modules and subsections have been constructed following consultations with key stakeholders. We would like to suggest that you consider the contents of this document prior to submitting a refined request, because information that is marked 'CCI' (Commercially Confidential Information), is highly unlikely to be released. For example, the majority of module 3 is commercially confidential information (information that pertains to the quality of a vaccine).

We would like to raise the below options for refinement:

- A narrowed request could focus on the clinical and non-clinical overviews (summaries of the data submitted in modules 4 and 5). In a similar manner to the dossier structure provided above, these documents can then be used to identify specific clinical or non-clinical studies that might be of interest to you. We have guided you towards the non-clinical and clinical data / information because much of the content on quality of medicines & vaccines is commercially sensitive, as mentioned above. In line with our previous response, we will not be able to provide any data that is commercially confidential or provided to the MHRA in confidence. We should add that exemptions may apply to parts of any documentation disclosed under FOIA.

  A refinement based on the overviews is an option which has often been recommended to members of the public requesting large amounts of information on regulatory approvals.

- While views will be sought from the Marketing Authorisation Holder, we have previously disclosed redacted versions of Risk Management Plans (RMP) for previous requests; as this is a smaller document than the full MHRA Assessment report, you may wish to proceed with a request for the RMP.

As set out below in your appeal rights, you may appeal against the decision to refuse the information at this time. However, we have discussed the future publication of the PAR (and the burden placed on those working to complete this process while also advising on requests for similar, and in some cases the same information, made to both the CHM and the MHRA). I therefore refer here to the suggestion made in our previous conversation, that it may be useful to resubmit a request at a future date, once you have had the opportunity to review the advice above and to consider the published PAR.

Medicines & Healthcare products
Regulatory Agency

You may request an internal review of the decision for this request by responding to this letter. If you disagree with the decision of the internal review, you may then appeal this to the Information Commissioner.

The Information Commissioner may be contacted at this address:

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

Or via their online complaints page:

https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

Lou Lander

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