Medicines & Healthcare products
Regulatory Agency

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Philip Hyland
By email: philip@pjhlaw.co.uk

8 August 2023

Internal Review: FOI 23/1045

Dear Philip Hyland

I am writing to provide the decision of the internal review for your information request FOI 22/1045, which was made on 12 October 2022.

Request history

Your request was set out at the beginning of your letter of 12 October 2022:

> *"I am instructed by the Health Advisory & Recovery Team (HART) to submit an FOIA Request to the MHRA requiring it to produce all data and all information* that was submitted by AstraZeneca in the application for license of their Covid-19 vaccine (AZD1222/Vaxzevria) and relied upon in granting a Conditional License for use.*
>
> ** I am instructed that a full data set and all information are:*
> *1. Pre- and post-authorisation safety and efficacy data for this product.*
> *2. All information that allowed a "rigorous scientific assessment" of all the available evidence of quality, safety and effectiveness by the UK Regulator, the Medicines and Healthcare Product Regulatory Agency (MHRA).*
> *3. All information and full data set that the MHRA stated their expert scientists and clinicians reviewed from the laboratory preclinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine and the conditions for its safe supply and distribution.*
> *4. Anonymised data from their clinical trials"*

Further explanatory paragraphs were then included in your letter. These are reproduced in the 'Request Correspondence' in the Annex to this letter.

The MHRA issued a response to the request on 9 November 2022. The response advised that:

> *"This information request in its current format would be exempt under s12 or s14."*

The response also provided advice on narrowing a new request, including a link to published information.

Following your letter of 13 April 2023, advising *"Considering that this peer review needs to be conducted on all material submitted for license, the request cannot be narrowed in scope",* the MHRA issued a further response to your request on 1 June 2023, confirming that section 14(1) applied to the request.

You requested a review of this decision on 13 June 2023. This is reproduced in full in the Annex.

Decision

This review considers that the MHRA correctly applied s14(1) to your request FOI 22/1045, as this request falls to be considered "vexatious" due to the scope of the request and the disproportionate burden that compliance would create. S14(1) of the FOIA states that *"Section 1(1) does not oblige a public authority to comply with a request for information if the request is vexatious".*

In the Information Commissioner's Office ("**ICO**") Decision Notice FS50493150, the ICO clarifies that the term 'vexatious' is not defined in FOIA. However, the ICO's guidance[1] also 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).*

[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

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. I appreciate that Paragraph 3 of the ICO guidance "*What do we do once we've decided to refuse a request under section 14?"* [5] indicates that when first refusing a request, a public authority is not required to explain why we may consider the request to be vexatious, advising that *"we appreciate that it may not be appropriate to provide a full explanation in every case."* However, for your request, this review finds that it would have been useful to provide further explanation in our final response of the burden that compliance with FOI 22/1045 would create, as this burden is the key factor in the application of section 14(1) in this case. I will include this explanation below.

The burden of compliance with the request

The information specified in your request is *all data and all information that was submitted by AstraZeneca in the application for license of their Covid-19 vaccine (AZD1222/Vaxzevria) and relied upon in granting a Conditional License for use"*.

The information provided to the MHRA by AstraZeneca, as described in your request and in the 4 explanatory points which accompanied your request, is contained in the regulatory dossier.

Downloading the dossier of the vaccine is a relatively straightforward task, although it does require time. Due to the voluminous size of the file packages, when downloading the full package of data, the database software may be more prone to freeze. However, the time required to read through the dossiers, to identify exempt

[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/

[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/what-do-we-do-once-we-ve-decided-to-refuse-a-request-under-section-14/

information and to consider and make redactions we expect would take many weeks, if not months to complete, as the dossier encompasses gigabytes of data.

To meet the request our staff:

- Would need to read the dossier in full, in order to identify where redactions need to be made.
- Extract the dossiers - as previously stated this is perceived to be a relatively straight-forward task but is not time negative.
- As per best practice and the FOI Code of 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, 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. The dossier contains full patient information, which we would need to manually review and redact in order to meet the request for 'anonymised data', as we do not hold this personal data 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 cannot; for example, the headings in a table of parameters could be disclosable, but the acceptance criteria are expected to be commercially sensitive. Some proposals for redactions will require input from different assessment teams to understand if the views put forward by the authorisation holders engage an exemption; for example, in instances where certain information is claimed to be commercially sensitive.
- We 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, 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 remains 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 has already devoted large amounts of time to creating resources that are in the public domain,

primarily the Public Assessment Reports (PARs) which include data that were integral to the benefit risk of the vaccines at the time of approval, especially the clinical safety and efficacy data.

In the vast majority of cases, our view is that the data included in the PARs, Summary of Product Characteristics (SmPCs) and other documentation such as that related to pharmacovigilance addresses the public interest surrounding the approval of the COVID19 vaccines.

Given the above, we do not believe that answering the request in full would represent a good use of resource. FOI requests are not required to be justified, but we note that you indicated that your request sought *"release of data for peer review"*. On this point, we 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 (https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership). 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.

The Information Commissioner's previous decision

I will here draw your attention to a previous decision issued by the Information Commissioner, as this concerned the same information to that specified in your own request. In IC-167627-X2Z0, the Information Commissioner considered the MHRA's application of section 14(1) to a request for *"all the data and information which the MHRA relied upon to give approval for the use of the Pfizer, AZ and Moderna covid-19 vaccines."* [6] While that request asked for all three dossiers, it is equally relevant to the breadth of the information contained in one dossier and the burden created by compliance with a request for one dossier alone.

In terms of the time needed to review a dossier, the Information Commissioner notes that *"The HMA/EMA documents provide some further clarification on this point. It provides an example Module 1-5 from a single dossier amounting to 33 pages."* The ICO went on to note, "*This example document only includes example data and headers for some categories so it is reasonable to assume that if it was populated with actual information the information could extend well beyond 33 pages for each dossier*."

I can add some further detail to the Information Commissioner's assessment based on the 'example dossier' of 33 pages only and explain that each of the modules within the dossier contains multiple documents. For this review, we sampled several documents from Module 5 of the dossier. In 5.3. 5.3 *Analysis of data from more than 1 study*, the length of the document we sampled was 10,410 pages. A document within 5.4 *Clinical Packages* was 18,185 pages long. (The MHRA's previous

[6] https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4022928/ic-167627-x2z0.pdf

responses advised that a review of all relevant information would exceed 300 hours, and this review considers that this is a minimum estimate.)

In the decision notice, it is particularly noted that:

- "[…]*the Commissioner has concluded that the MHRA were entitled to refuse to comply with the request on the basis of section 14(1) of FOIA*."
- the ICO agrees that for considerations of the public interest under section 14(1), that interest was served by the inclusion of the main findings and outcomes of the non-clinical and clinical assessments in the Public Assessment Reports and other published information.
- The Information Commissioner agreed that potentially exempt information appears throughout a dossier and cannot be easily isolated. This indicates that the burden on resource necessary to trigger Section 14(1) can be met when detailed and careful redactions are required to voluminous material.
- The Information Commissioner was particularly concerned that different types of personal information are spread throughout the dossier, and that the MHRA would need to identify the personal data in each case and then determine which category it fits into before determining if it should be redacted or not.
- Paragraph 49 of the decision notice concludes that:

> *"However, it is precisely because of the volume and complexity of information in the scope of the request that has led the Commissioner to accept that the burden placed on the MHRA in complying with it is a grossly oppressive one. In the Commissioner's opinion despite the clear value in the disclosure of this requested information, he does not accept that this is sufficient to justify placing such a burden on the MHRA and expect it to undertake a significant amount of time to process this request. This is particularly relevant as the MHRA did go to lengths to attempt to be of assistance in refining the request, providing significant detail on how the information is structured in the dossiers and what might be disclosable if the request was narrowed – suggestions that were all rejected."*

Conclusion

On the basis of the above, section 14(1) applies to the request for the dossier containing *"all data and all information provided by AstraZeneca in the application for license of their Covid-19 vaccine (AZD1222/Vaxzevria) and relied upon in granting a Conditional License for use"*.

Advice and assistance

The remainder of this letter will provide a description of this dossier below with a view to providing advice and assistance on how you may narrow your request.

Medicines & Healthcare products Regulatory Agency

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 consider the individual documents or studies from the regulatory dossier you may be most interested in.

To make sure that any redactions we propose to regulatory dossiers are in line with established principles, we routinely follow the 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

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 the vaccine).

We would also like to raise the below option for refinement, that:

- 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, and these can subsequently be requested through FOI. 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. Also, as you are aware, the studies used to support the assessment are also detailed/summarised in the Public Assessment Report available on this page:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

We hope this will be of assistance to you, and that the further explanation provided in this review is useful.

If you disagree with the decision of the internal review, you may make an appeal 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

FOI Manager
MHRA Customer Experience Centre
Communications and Engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4P

Medicines & Healthcare products Regulatory Agency

Annex: Request Correspondence

Your request was set out at the beginning of your letter of 12 October 2022:

> *“I am instructed by the Health Advisory & Recovery Team (HART) to submit an FOIA Request to the MHRA requiring it to produce all data and all information* that was submitted by AstraZeneca in the application for license of their Covid-19 vaccine (AZD1222/Vaxzevria) and relied upon in granting a Conditional License for use.*
>
> ** I am instructed that a full data set and all information are:*
> *1. Pre- and post-authorisation safety and efficacy data for this product.*
> *2. All information that allowed a "rigorous scientific assessment" of all the available evidence of quality, safety and effectiveness by the UK Regulator, the Medicines and Healthcare Product Regulatory Agency (MHRA).*
> *3. All information and full data set that the MHRA stated their expert scientists and clinicians reviewed from the laboratory preclinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine and the conditions for its safe supply and distribution.*
> *4. Anonymised data from their clinical trials”*

Further explanatory paragraphs were then included in your letter following the request:

> *“<u>Statement on the information</u>*
>
> *The government has invested millions of taxpayer's monies to develop and market the AstraZeneca vaccine.*
>
> *Therefore, it would not be in the public interest if the medical and scientific community do not have access to the complete set of AstraZeneca vaccine data and information.*
>
> *Releasing this data should also enable independent scientists to confirm or otherwise, MHRA's conclusion and often repeated declaration that the AstraZeneca vaccine is 'safe and effective'.*
>
> *<u>Statement on Transparency</u>*
> *FOI 21/1225 - In reply 15.12.21 ".... MHRA are committed to transparency".*
>
> *<u>Statement on FOIA</u>*
> *FOIA is to ensure informed citizenry - vital to the functioning of a democratic society, to open the veil of administrative secrecy and to open the agency actions to the light of public scrutiny.*

FOIA provides an opportunity to develop a relationship with the public based on openness and transparency as stated by the Information Commissioner's Office.

The principle behind the Act is to release information unless there is a good reason not to.

We believe that the public interest test can be applied to:
Section 41 (Information provided in confidence)
Section 43 (Commercial interests)
and that test is the safety of the nation's health.

2407 people had applied for vaccine injury compensation by August 2022. HMG has now acknowledged that death/serious injury has been caused by Covid-19 vaccination by paying out the first 12 victims from the Vaccine Injury Compensation Program. I also note that Coroners Courts are registering deaths because of Covid-19 vaccination.

Access to the requested records should be granted within 20 business days from the date of receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and all legal rights are reserved."

The MHRA issued a response to the request on 9 November 2022. The response advised that:

"This information request in its current format would be exempt under s12 or s14.

Section 12

Section 12 applies when the cost exceeds then limit of 24 hours to determine if the information is held, locate, retrieve, and extract the information. We estimate the time taken to conduct the above activities to be in excess of 36 hours.

Section 14

A Section 14. refusal, can be used in situations where handling multiple requests or a single request, would lead to a grossly excessive burden being placed on the public body or institution. We expect that this burden would be incurred due to the need to read, consider, and apply redactions, to the vast array of regulatory material encompassed by the request. We expect the time taken to conduct redactions to be >300 hours.

In line with the ICO advice, we would suggest that your client considers a refinement of their request before a formal refusal notice is issued. An example of refinement would be for your client to review the public

> *assessment report below, and select a certain study or concept which they find of particular interest. Then should they wish to, your client/s can lodge a refined request or requests. Please note, we cannot guarantee that a request refined in a manner that for example, selects a particularly wide concept area or a major study would not still fall outside the limits of S.12 or prevent a S.14 refusal.*
>
> *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_dat a/file/1103097/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_16.07.2021.pdf*
>
> *Should your client consider that they cannot narrow the scope of their request, the Agency will consider it to appropriate to apply S.14."*

Following your letter of 13 April 2023, advising that "*"Considering that this peer review needs to be conducted on all material submitted for license, the request cannot be narrowed in scope",* the MHRA issued a further response to your request on 1 June 2023:

> *Thank you for your information request, dated 12 October 22 and your further correspondence of 12 April 2023, where you confirmed your request as follows: "I am instructed by the Health Advisory & Recovery Team (HART) to submit an FOIA Request to the MHRA requiring it to produce all data and all information* that was submitted by AstraZeneca in the application for license of their Covid-19 vaccine (AZD1222/Vaxzevria) and relied upon in granting a Conditional License for use.*
>
> ** I am instructed that a full data set and all information are:*
>
> *1. Pre- and post-authorisation safety and efficacy data for this product.*
> *2. All information that allowed a "rigorous scientific assessment" of all the available evidence of quality, safety and effectiveness by the UK Regulator, the Medicines and Healthcare Product Regulatory Agency (MHRA).*
> *3. All information and full data set that the MHRA stated their expert scientists and clinicians reviewed from the laboratory preclinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine and the conditions for its safe supply and distribution.*
> *4. Anonymised data from their clinical trials" The purpose of this request as stated in your letter of 12 October 2022 is 'so that independent scientists can review it [is] akin to asking for a second opinion from a doctor, or a peer review of a scientific paper.'*
>
> *A copy of the request and further correspondence is available at Annex A. In summary, on the 9 November 2022, the MHRA informed you that such a request would fall under s12 (exceeds 24 hours) or s14 (vexatious). Before applying such an exemption, and in line with ICO best practice, we asked your*

client to consider refining their request to, for example, a certain study or concept of particular interest.

In your correspondence of 12 April 2023, you confirmed on behalf of your client that "Considering that this peer review needs to be conducted on all material submitted for license, the request cannot be narrowed in scope". As indicated in our November response, the Agency is now applying the s14(1) FOIA exemption.

The MHRA are not required, at this stage, to explain why we consider the request to be vexatious (3rd paragraph of ICO guidance "What do we do once we've decided to refuse a request under section 14?"). However, the MHRA considers section 14(1) FOIA applies based on the burden that would be placed on the MHRA and its staff to comply and consideration that the public interest test balance does not sit in favour of release.

Overview of s14(1)

S14(1) of the FOIA states that "Section 1(1) does not oblige a public authority to comply with a request for information if the request is vexatious".

Information Commissioner vs Devon County Council & Dransfield [2012] UKUT 440 (ACC), (28 January 2013) defined the purpose of section 14 as follows: "The purpose of Section 14…must be to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of the FOIA…" (paragraph 10)

Application of s14(1)

Your request of 12 April 2023 asks us to consider that you are requesting an internal review if we apply Section 14 to the request. However, our process for handling requests under the Freedom of Information Act is that we will provide our reply and give the requestor the opportunity to request an Internal Review should they be dissatisfied with how their request has been handled. Our reply of 09 November 2022 made reference to both Section 12 and Section 14, whereas we are now applying Section 14 only. Accordingly, we consider this letter to be our substantive response to your original FOI of 09 November 2022."

You requested a review of this decision on 13 June 2023:

"Re: HART, REQUEST FOR INTERNAL REVIEW OF FOI [22/1045]

This firm is instructed by HART in connection with a request for release of data for peer review.

In your letter of 1st June 2023, you state that you are applying the s14(1) FOIA exemption in response to the above FOI.

"The MHRA are not required, at this stage, to explain why they consider the request to be vexatious, but the MHRA considers section 14(1) FOIA applies based on the burden that would be placed on the MHRA and its staff to comply and consideration that the public interest test balance does not sit in favour of release".

The MHRA reviewed all the Astra-Zeneca (AZ) vaccine data within a 3-month period from end September 2020 until it was authorised on 30th December 2020 and first used on 4th January 2021. There was a time overlap with the MHRA's review of the Pfizer and later the Moderna data. This was not declared a burden of work placed on the MHRA.

Consideration should be given to a staggered release of the AZ data, over an agreed timeframe, of the AZ license application data.

Application for Internal Review

We are dissatisfied with how FOI [22/1045] request has been handled and therefore request an Internal Review as is our right, and we have submitted this request within 2 weeks of the response date.

We hope that the MHRA will forthwith review our request and agree to produce responsive records. We reserve all rights until these issues have been properly resolved.

We disagree with how MHRA have interpreted the Freedom of Information Act 2000 in answering this request and again, this is why we are asking for an internal review.

Challenging the section 14 refusal

Section 14 of the Act ('vexatious' requests), is the MHRA's exemption of choice. It is appropriate to note that in 2005, the House of Commons Health Committee expressed concerns:

• Pharmaceutical funding would lead the MHRA to "lose sight of the need to protect and promote public health above all else as it seeks to win fee income from the companies".
• The Committee also criticised the MHRA saying that it "failed to adequately scrutinise licensing data and its post-marketing surveillance is inadequate".
• "Greater transparency is also fundamental to the medicines regulatory system. There has to be better public access to materials considered by the MHRA prior to licensing".

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Statement on FOI

The entire purpose of FOIA is government transparency and this FOIA request is of paramount public importance.

Information is often useful only if it is timely; excessive delay by the agency in its response is often tantamount to denial.

FOI provides an opportunity to develop a relationship with the public based on openness and transparency.

The FOI self-assessment toolkit is produced by the Information Commissioners Office (ICO) which states:

• Openness is fundamental to political health of a modern state.
• Public authorities spend money collected from taxpayers and make decisions that can significantly affect many people's lives.
• Access to information helps the public make public authorities accountable for their actions and allows public debate to be better informed and more productive.
• Unnecessary secrecy in government leads to arrogance in governance and defective decision-making.

FOIA is to ensure informed citizenry - vital to the functioning of a democratic society, to open the veil of administrative secrecy and to open the agency actions to the light of public scrutiny.

"A nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of the people".
John F Kennedy

FOIA provides an opportunity to develop a relationship with the public based on openness and transparency as stated by the Information Commissioner's Office.

The principle behind the Act is to release information unless there is a good reason not to.

Exemptions

The MHRA's web site sets out a clear commitment: "The agency's guiding principle is full transparency unless non-disclosure is justified on the basis of established freedom of information exemptions".

Most exemptions are not absolute but require a public interest test be applied. This means the MHRA must consider the public arguments before deciding whether to disclose the information.

To justify withholding information, the public interest in maintaining the exemption would have to outweigh the public interest in disclosure.

The principle behind the Act is to release information unless there is a good reason not to. Therefore, information can fall within an exemption, but public interest can favour disclosure.

We request that you re-examine the Public Interest Test and that test is the Safety of the Nation's Health.

"Excessive administrative secrecy ... feeds conspiracy theories and reduces the public's confidence in the government".
John McCain

Protecting the MHRA rather than the Public

We have been seeking access to materials supporting the MHRA's decision to authorise the AstraZeneca COVID-19 novel vaccine, Vaxzevria. It has been disproportionately associated with adverse reactions and those damaged by it are being largely ignored by the authorities, especially the MHRA. Important information is being withheld from the public which has a right to see all the AZ vaccine data provided by AstraZeneca to the MHRA.

-Statement on the Information requested:

The government has invested millions of taxpayer's monies to develop and market the A-Z product. The government has coercing millions of people, most of its population, to be injected with a liability-free vaccine and therefore requires complete government transparency, not suppression of information. Therefore, it would be incredibly unfair to the British people to not have access to the Astra-Zeneca data and information.

Reviewing this information will settle the ongoing public debate regarding the inadequacy of the MHRA's review process. Releasing this data should also confirm MHRA's conclusion and often repeated declaration that the A-Z vaccine is "safe and effective" and therefore increase confidence in the vaccine.

The medical and scientific community and the public have a substantial interest in reviewing the data and information underlying the MHRAs approval of the AZ vaccine.

The public's need for this information is urgent given the fact that vaccination programmes are continuing. The ICO suggest that a review should be completed within 20 business days from the date of receipt of this letter.

Failure to respond in a timely manner shall be viewed as a denial of this request and all legal rights are reserved.

Thank you for your time and attention to this matter."