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Information Commissioner's Office
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30th September 2023

RE: ICO Challenge of Response to FOI 22/1045

I am the author[1] of an FOI request[2] on behalf of HART (Health Advisory & Recovery Team) and instructed PJHLaw Solicitors LLP to review and send to the Medicines & Healthcare Regulatory Authority (MHRA), requesting that the MHRA **fully produce all the data, information and documents** submitted to them by **AstraZeneca (AZ)** that underlies the Conditional Marketing Authority (Temporary License) of the AZ Covid-19 vaccine.

On 1 June 2023, MHRA confirmed that section 14(1) applied to this request. An internal review was requested on 13 June 2023 and received on 8 August 2023.

Internal Review[3] 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".

"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."

I challenge both parts of this decision:

A. The disproportionate burden.
B. The public interest does not outweigh the resource burden.

A. <u>Challenging the Disproportionate Burden</u>
1. *Time to produce.*
All Regulators globally were given the same documentation for license application on each Covid-19 vaccine from September 2020. The information is produced as a Common Technical Document by each manufacturer.

We know the size of this data[4].
There is now a precedent as the US Regulator, the FDA, was court ordered to release both the Pfizer and Moderna vaccine documents. This is the schedule:

- Pfizer must produce 451,000 pages at a rate of 55,000 pages a month (as opposed to the 75 years the FDA wanted to take). This will be completed in a few more months.
- Moderna vaccine data (plus Pfizer vaccine data for 12-15yr olds) is much larger at 4.8million pages and will be released from the FDA at 180,000 pages a month which will take about 26months to mid-2025, (as opposed to the 23.5years the FDA wanted to take).

These are being analysed on release and published as the Pfizer Document Analysis[5].

Suggestion:
The AZ data could be produced over a timed schedule and released accordingly.

The MHRA were able to review the AZ data in record time over the period from 24/09/2020 to 29/12/2020[6]. Please take note that a "robust" review of all this data was completed in 3 months, a fraction of the normal time frame (5-7years). They were also reviewing the Pfizer data at the same time, implicating that they can review this amount of information quickly.

At Public MHRA Board Meetings, they confirmed staffing levels were 25% below normal during this period in the last 6months of 2020. It is malfeasance to blame lack of staff when the MHRA is responsible for Pharmacovigilance to protect the public's health. The MHRA came into existence because of the teratogenicity of Thalidomide, and to protect the public from similar experiences.

Given MHRA's apparent speed-reading abilities + AI tools, such a schedule should be doable.

2. *Downloading dossier is a problem as software more prone to freeze.*
This is a nonsense as we know from the 3250 analysts involved in the Pfizer Document Analysis who do not have a problem with their software freezing.
a. The COO of the Pfizer Document Analysis[5] has stated that they make available an Abstractor's (https://vaccines.shinyapps.io/abstractor/) ability to search all Pfizer PDFs released to date and that a team of 2-3 people set up a database that contains all of the XPT data files released by Pfizer to date.
b. Additionally, on the PHMPT's website it allows one to download the entire production to date (PDFs + XPT files + XML files + etc.).

Question: Is the MHRA so backward with its systems, even though they are responsible for Pharmacovigilance?

Statement: Using inefficiency as a reason for the burden is not valid.

3. *Redactions and identifying exempt information would take many months.*
The COO of the Pfizer Document Analysis has confirmed there have been some documents that are heavily redacted, but most are not. Why would the AZ documents not be in a similar format?

Suggestion: Release documents that "need" heavy redaction later in the production, thus giving more time on those documents.

4. *Extracting dossiers takes time*
This is true, but it's also true that this is one of the things that citizens of the UK are paying them to do.

5. *Reading the dossier in full to make redactions.*
Trial participants' information must be redacted but most are already anonymized as each trial participants is normally allocated an unidentifiable Unique Subject ID.

If the MHRA received personal information of authors, trial participants, patients to the Regulators, that they forward to Independent Panels without it being redacted?

We know that in the Pfizer trial documents provided by the FDA, most trial participant data is already anonymized and in many cases, information on authors, investigators, etc. isn't redacted, but this has been passed on under the US court order.

6. ***Expect almost all documents to require some form of redaction.***
The COO of the Pfizer Document Analysis has stated based on the gigs and gigs of Pfizer documents released so far, as well as some Moderna ones, that she knows that this is not true and suggests that most documents will not require redaction.

How does the FOI Manager know how much redaction is required, as no-one at the MHRA will have read the whole of the documentation?

7. ***Solicit views from third parties to consider proposals against transparency guidelines/FOI exemption criteria.***
In 2005 a House of Commons Health Committee expressed concerns which have not been addressed:
i) 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".
ii) The Committee also criticised the MHRA saying that it "failed to adequately scrutinise licensing data and its post-marketing surveillance is inadequate".
iii) "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".

This begs the question, "What are the MHRA hiding?" UK citizens paid with tax for everything that was utilised during the pandemic and the AZ Covid-19 vaccine. For that reason alone, transparency should be the default and would be consistent with the principles governing office holders.

8. ***Manual review of full patient information to review/redact.***
Is everything done manually by the MHRA?

What happened to the £1.5 million grant they received for AI as they expected 100,000 Yellow Card reports, more than ever received before? The MHRA need to disclose if the AI has not been implemented given the grant size.

They can get around the misspellings issues mentioned by searching with alternative spellings or doing searches based on part of a word (e.g. search on "pharma" instead of "pharmaceutical"). Surely they do not expect us to believe for a minute that there is an army of Redactors sitting somewhere in the MHRA going page-by-page and using Adobe to redact documents?

9. ***Redactions must be made irreversible***
This is a false flag.

- If the MHRA are using Adobe, it tells you as you redact that it's permanent.
- If the MHRA are using AI, that should just be a setting in the tool.

Statement:
This internal review seems to have been written by someone who does not understand the MHRA system and is not aware that information is already in the public domain.

B. <u>Challenging the Public Interest does not outweigh the resource burden.</u>

1. *"MHRA do not feel that the Public Interest in Covid-19 vaccines outweighs the resource burden required to meet your request"*.

What would the public say if they knew Public Health is not being put before convenience for the MHRA?

Knowing what we know now after over 2.5 years of the roll-out of the Covid-19 vaccines, this would be an unbelievable statement to many.

This statement states the needs of the MHRA are greater than the protection of the public's health and safety. The government decided in 2005 that information considered for licensing, should be available after licensing.

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

We know from the Pfizer data release that the PAR and SmPC do not match the data provided to Regulators for license application.

We need to see if the information we are being told in the MHRA PAR and SmPC reports for the AZ Covid-19 vaccine matches the AZ data directly supplied by the manufacturers.

Transparency is needed because the license that states, "Vaxzevia is a vaccine used for **preventing** Covid-19 caused by a virus called coronavirus (SARS CoV-2)," has been broken because many of those injected multiple times have had the infection multiple times, i.e. it has not prevented infection in the vaccinees.

3. *Public Assessment Reports (PARs) and Summary of Product Characteristics (SMPCs), including data that were integral to the benefit-risk of the vaccines at the time of approval, especially the clinical and efficacy data and documentation on pharmacovigilance addresses the public interest surrounding the approval.*

These are the MHRA interpretations of the data. This is not the same as the public having access to make its own determinations. We can only know if the information is correct once we see the data.

The MHRA's proactive safety monitoring plan - the Yellow Card Vaccine Monitor (YCVM) has shown high adverse drug reactions (ADRs) – this information has only been reported to the PEAG. The MHRA's Yellow Card Monitor was completed at regular intervals by people following vaccination. In the YCVM Group, 53% reported

at least one ADR by 30 June 2021; the AZ vaccinees = 59.2% reported at least one ADR. A major safety signal all round but especially for AZ.

This is MHRA's own data from its own monitor and still it does not make the public aware. There are 1366 pregnant women studied on the YCVM. Those taking the AZ vaccine, a whopping 66% (124 out of 203) reported at least one ADR. What do the SmPC and PAR reports say on pregnancy?

SmPC[7] - updated latest report from 6.23 PAR[8] - updated latest report from 3.23
Pregnancy

- There is a limited experience with the use of COVID-19 Vaccine AstraZeneca in pregnant women.
- Administration of COVID-19 Vaccine AstraZeneca during pregnancy should only be considered when the potential benefits outweigh any potential risks (including those described in sections 4.4 and 4.8) for the mother and fetus.

and yet it has been promoted in pregnancy by the NHS and MHRA.

4. *MHRA operates licensing procedures in conjunction with advice and decisions of independent panels[9] (expert groups) i.e. CHM Members.*

How Independent are these Panel members of mainly University Professors? Do they disclose their conflicts of interest? The "independent" MHRA gets 86% of its funding from Pharma and they have grants from B&MG Foundation.

Over three months, the MHRA claim they had time for the independent groups to review all this information as well as themselves.

The chair of CHM helped launched the AZ vaccine[9]. We know from the Pfizer Documents that Pfizer presented to the Advisory Committees. The MHRA subserved to Pfizer and they, Pfizer, told the Regulatory Authorities, what the data shows. This is a "Bait and Switch". Did AZ also present to the MHRA?

2 billion doses of AZ Covid-19 vaccines have been distributed to 170 countries, with 50 million+ administered in the UK.

4. *PARs and SmPC documentation related to pharmacovigilance addresses the public interest surrounding the approval of the Covid-19 vaccines*.

How do they know that these documents address the public interest? The MHRA is responsible for Pharmacovigilance and therefore the public needs to see if they have been vigilant in their assessment of the data.

Safety:
Covid 19 vaccines have recorded more ADRs and deaths on the MHRA's Yellow Card System than with any other products and more than the total for vaccines over 40 years. 58% of reports including deaths, were for the AZ vaccine.

Reported deaths and ADRs have not been followed up by the MHRA.

Coroners' courts have certified deaths, stating AZ vaccine injury. AZ know deaths have been caused by their vaccine as AZ and HMG lawyers "attended" Coroner's inquests via Teams. By January 2023, HMG had acknowledged that death/serious injury has been caused by Covid-19 vaccination by paying out the first 33 victims from the Vaccine Damage Payment Scheme.

The ABPI Code of Practice for the Pharmaceutical Industry (6.4) states the word "SAFE" cannot be used without qualification.

Effectiveness:
The MHRA were happy to promote the RRR (AZ=66.84%) for effectiveness which is known to exaggerate. The ABPI Code of Practice for the Pharmaceutical Industry (6.1 *Supplementary*) states they are only allowed to use the ARR (AZ=1.28%) on its own for effectiveness, as it is the truer statistic.

Quality:
MHRA is supposed to inspect the manufacturer to ensure GMP. We know there are inconsistencies in the vial contents, breaking GMP legislation. There are contaminants in the vaccines and therefore the products are not reliably consistent**.**
Safety checks were not done on these multiple vials, as they went from multiple manufacturers to the arm.

In the EMA's PAR for AZ vaccine there are 55 Recommendations and 36 of these are Quality issues.

Challenge of the Internal review:

- The principle behind the FOI Act is to release information; public interest can favour disclosure.
- This exemption (s14) is not absolute, and a public interest test must be applied.
- The public test should be the Safety of the Nation's Health.
- The public interest in disclosure far outweighs the public interest in maintaining the exemption (s14).

Summary:
The mission of speed driving the vaccine development and implementation, bypassed the pre 2020 clinical safety protocols, resulting in high injury and fatality figures world-wide as ethical safeguards are dissolved.

Dame June Raine, CEO, stated the MHRA overcame "obstacles" within the structure of clinical trials to license vaccines in the UK faster than anywhere else because of their "flexibility yet **robustness"**.[10] An unnecessarily hurried approach, results in no long-term safety data.

In summary, these are novel vaccine technologies, delivered by novel methods, approved using novel clinical trials regulations, at novel speed and causing unacknowledged novel numbers of ADRs. As stated, in 2005 a House of Commons Health Committee expressed concerns stating, **"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".**

Protection of the Nation's Health:
By the end of 2022 the public had reported 2,404 deaths connected to the vaccines on Yellow Card, a system estimated to record <10% of actuals.

Previously, vaccines (1976 Swine flu & 2009 Pandemrix) have been withdrawn from market with less than **50** deaths.

The public have been asked to take this vaccine without data on content, without informed consent, and without any patient information. Raw data surrounding all the vaccines and the contracts involved, have been shrouded in secrecy.

Concluding remarks:

- The government has invested millions of taxpayer's monies to develop and market the AZ vaccine and has coerced a large percentage of its population, to be injected with a liability-free vaccine and therefore we require complete government transparency, not suppression of information.
- It would show utter contempt for our democracy if the British public were denied access to the AZ data and information.
- The medical and scientific communities and the public have a substantial interest in reviewing the data and information underlying the MHRA's approval of the AZ vaccine.
- If the MHRA's due diligence has been thorough, then releasing this data should confirm their oft repeated declaration that the AZ vaccine is safe and effective, thus providing reassurance to the public.

We hope to receive a positive response to this complaint re the internal review of FOI (22/1045) and ask for a reply within 20 days of receipt.

Yours sincerely,

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(dilearn@ntlworld.com)

REFERENCES

1. Confirmation of link to FOI

2. FOI Request (FOI 22/1045), Response, Internal Review Request

3. Internal Review from MHRA

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6. Time taken for the robust review
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7. SmPC: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for

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9. Independent Panels:
https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership

10. Dame June Raine (MHRA) and Professor Sir Munir Pirmohamed (CHM)
https://www.youtube.com/watch?v=yjbL2RFNUMc