[redacted]

From: [redacted]
Sent: 12 May 2021 16:13
To: Pharmacovigilanceservice; [redacted]
Subject: RE: Internal Review - RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website
Attachments: FOI 21-276 response.pdf; FOI 21.276 Inernal Review 120521.doc

OCLink: 893411ef-0287-4197-9ea4-7037bded6df9

[redacted]

Please find attached a letter to be sent to the FOI enquirer setting out my findings in the review of FOI 21-276. Could you please put on the MHRA headed paper in pdf form and send to Mr Suadoni. You will need to include the previous correspondence in the reply email. Can I please have a copy of the final version.

Thanks.

Jan

Jan MacDonald
B.Sc. M.Sc. M.R.Pharm.S.
Group Manager Access & Information for Medicines & Standards (job share)
VRMM

MHRA
10 South Colonnade,
Canary Wharf,
LONDON
E14 4PU

Telephone: 020-3080-6267
[redacted]

I work as a job share with Beryl Keeley. We each work 3 days/week (Monday to Wednesday or Wednesday to Friday). Please reply to this email address and one of us will be available to respond.

MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency

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From: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Sent: 20 April 2021 18:39
To: [redacted]
Subject: RE: Internal Review - RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

Hi Jan and Beryl,

Thank you for helping with this review. Please find attached the response we sent. Let me know if you need any other information.

Kind regards,
[redacted]

From: [redacted]
Sent: 20 April 2021 17:30
To: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Cc: [redacted]
Subject: RE: Internal Review - RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

Hi [redacted]

Jan MacDonald and Beryl Keeley will look at this.

Thanks
[redacted]

From: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Sent: 20 April 2021 14:41
To: [redacted]
Cc: [redacted]
Subject: FW: Internal Review - RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website
Importance: High

Hi [redacted]

Please can this internal review request be allocated?

Many thanks,
[redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: 19 April 2021 20:17
To: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Cc: [redacted]
Subject: Internal Review - RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website
Importance: High

Internal Review of FOI 21/276

Dear All,

This request has been logged as internal review and the 20 day deadline for this request is 18 May 2021.

We are grateful for your help with this internal review.

Kind Regards

[redacted]
MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Sent: 19 April 2021 12:25
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; [redacted]
Cc: [redacted]
Subject: FW: RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

Hi Team,

Can this be logged as an internal review request.
[redacted] – FYI this was a Section 22 response for iDAPs.

Kind regards,
[redacted]

From: Marco Tullio Suadoni <marco.suadoni@pm.me>
Sent: 19 April 2021 12:04
To: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Subject: Fw: RE: FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

To:
Communications Directorate
Medicines and Healthcare products Regulatory Agency

Dear Sir or Madam,

Re: Request of review of response to 'FOI 21/276 - Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website'

I would ask if you would review the decision enclosed in attached letter. As a vaccine centre supervisor, with the responsibility of overseeing clinical practice, including ensuring informed consent to treatment, 5 months well into a mass vaccination programme and with the level of information technology nowadays available (and recently specifically purchased by the MHRA for the management of covid-19 vaccine pharmacovigilance infrastructure), I believe there are little reasons for not making the information I requested immediately available to myself individually, or, even better, to the public, and especially professionals and researchers. The technology is there, and cheap. I can offer to the MHRA a free cloud service open to public view, personally hosted in my home.

Yours faithfully,

Marco Tullio Suadoni

Sent with ProtonMail Secure Email.

------- Original Message -------
On Monday, April 19th, 2021 at 10:55 AM, Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk> wrote:

Dear Mr Suadoni,

Please find attached the response to your FOI request.

Kind regards,

FOI Team

Vigilance and Risk Management of Medicines Division

Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: Marco Tullio Suadoni <marco.suadoni@pm.me>
Sent: 19 March 2021 10:46
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

CHM

To whom it might concern:

Dear Sir or Madam,

Re: Freedom of Information Act Request of adverse drug reaction (ADR) data regarding all Covid-19 vaccines in use in the UK which is not available on gov.uk website

First of all, I am aware of the information available here: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

However, the information linked as above does no report all ADRs data, but only summary data.

I request in spreadsheet or database format, e.g., comma-separated-values (CSV) (not PDF format), the full body of all anonymised raw data with the level of details as close as possible to that one available for Interactive Drug Analysis Profile (iDAP) and related CSV files, for all Covid-19 vaccines currently in use in the UK. Especially to include for EACH event, but not limited to:

SEX

AGE

DATE

REPORTER

REPORT SUBMISSION

ROUTE OF ADMINISTRATION

SERIOUSNESS

SYSTEM ORGAN CLASS

Yours faithfully,

Marco Tullio Suadoni

Sent with ProtonMail Secure Email.
