Medicines & Healthcare products Regulatory Agency

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

9 August 2023

Dear [redacted]

FOI 23/474

Thank you for your email of 26 June 2023 where you requested the following:

'*In relation to its Covid vaccine product authorised for use in the UK, please could you confirm for each calendar year from 2020 to 2023 how many validated safety signals have been notified to the MHRA by Pfizer/BioNTech by means of:*

(a) a product information and/or RMP variation application or equivalent?

(b) inclusion in a PSUR?

(c) a standalone signal notification (including any signal also notified in a PSUR but which has been separately notified as an 'important risk')?

Separately, can you please provide a copy of each of the PSURs provided to the MHRA by Pfizer/BioNTech in relation to its Covid vaccine product during the period since 1 January 2021'.

Please see the information requested below.

a) The MHRA is not notified of signals via Risk Management Plans (RMPs) or product information updates.

b) and c) Safety signals notified to the MHRA by Pfizer BioNTech are documented in the Periodic Safety Update Reports (PSURs). We can confirm that the MHRA holds copies of the following requested Periodic Safety Update Reports (PSURs):

- **PSUR 1** 19 December 2020 to 18 June 2021
- **PSUR 2** 19 June 2021 to 18 December 2021
- **PSUR 3** 19 December 2021 to 18 June 2022
- **PSUR 4** 19 June 2022 to 18 December 2022

Please see section 15 of each the PSURs for an overview of signals (new, ongoing or closed during the reporting period).

These documents are provided with this response. Information that has been redacted is exempt under Section 40 (Personal Information). Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles.

For further information about the purpose of PSURs, please see the Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report available at: Good pharmacovigilance practices | European Medicines Agency (europa.eu)

Please note that in addition to the signals included in the above PSURs, Pfizer BioNTech also notified the MHRA of a signal of myositis in association with COVID-19 vaccine Pfizer BioNTech in 2023.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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