Medicines & Healthcare products Regulatory Agency

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[redacted]

2 June 2023

FOI 23/162

Dear [redacted]

Thank you for your email of 27 February 2023 where you requested information on safety signals concerning COVID-19 vaccines. Please accept our apologies for the delay in responding to you.

The MHRA does hold some of the information requested. However, we have also determined that some of the information is exempt under Section 12 of the Freedom of Information Act. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving, and extracting the information.

1. **In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 how many notices of a safety issue which meets the applicable definition of an 'emerging safety issue' have been received by the MHRA from Marketing Authorisation Holders for those vaccine products? And of those notices received by the MHRA how many are known to have been received more than 3 working days after the reported date of establishment of that emerging safety issue (i.e. late-filed notices)?**

The MHRA received two notifications of emerging safety issues COVID-19 vaccines between December 2020 and March 2023. Neither was received more than 3 working days after the reported date of establishment of the ESI.

It should be noted that in the UK and EU, the COVID-19 vaccines were subject to enhanced safety monitoring, involving regular meetings with the manufacturers and also a requirement for more frequent summary safety reporting by the manufacturers (monthly rather than 6 monthly). This likely impacted the number of ESI notifications received for the COVID-19 vaccines.

2. **In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 how many validated signals have been notified to the MHRA by MAHs 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')?

There are 10 COVID-19 vaccines currently authorised in the UK. As the information requested in question 2 would require manual searches for each vaccine, we have determined that the requested information is exempt under Section 12 of the FOI Act. Should you wish to refine this request to specific vaccines, the MHRA may be able to provide a response.

3. **In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023, on how many occasions has the MHRA been notified of the initiation of a safety referral procedure that affects any such product?**

The MHRA has not been notified of any safety referrals concerning COVID-19 vaccines between 2020 and March 2023.

4. **As part of pharmacovigilance procedures in relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 on how many occasions has the MHRA received from MAHs notice (of any kind) of a suspected adverse event expressed to have been triggered by one or more members of the public reporting a suspected adverse event via social media?**

Up to and including 13th March 2023, the MHRA has received a total of 15,121 UK spontaneous Adverse Drug Reaction (ADR) reports directly from pharmaceutical companies concerning the COVID-19 vaccines.

There is no structured field whereby the reporting pharmaceutical company can specify that the report came from social media, and manually searching each of these 15,121 ADR reports would exceed the time limit defined under the Freedom of Information (FOI) act. We have therefore performed a free text search on the narrative of each of these 15,121 for the words 'social media'. This search identified a total of 64 UK spontaneous ADR reports, which are broken down by year below:

Year initial date received by MHRA	Number of ADR reports
2021	15
2022	38
2023	11

Please note that reports originating from social media which do not contain the words ‘social media’ in the narrative will not be included within this search. When considering the data you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine or vaccine may have caused the adverse reaction. The existence of an adverse reaction report on our database does not necessarily mean that the vaccine has caused the suspected reaction.

- It may be difficult to tell the difference between something that has occurred naturally and a suspected adverse reaction. Sometimes these events can be part of the condition being treated rather than being caused by the vaccine.
- Many factors have to be considered when assessing whether the vaccine has caused a reported adverse reaction. When monitoring the safety of vaccines and medicines, MHRA staff carry out careful analysis of these factors.

5. **In relation to the Covid vaccine products currently authorised for use in the UK, in the period from January 2020 to 2023 on how many occasions has the MHRA commenced either (i) a major safety review or (ii) any other safety review which falls short of a major safety review in response to a new safety signal or to support effective risk minimisation?**

The MHRA has not initiated any major safety reviews in relation to COVID-19 vaccines between January 2020 and March 2023.

Details of other safety reviews undertaken by the MHRA are included in the MHRA's summary of coronavirus adverse reaction reporting here.

I hope this information is helpful.

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
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