Medicines & Healthcare products
Regulatory Agency

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London
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United Kingdom
gov.uk/mhra

9 August 2023

Dear [redacted]

FOI 23/428

Thank you for your email of 19 June 2023 where you requested the following:

1. *I request the total number of individuals from England and Wales who have reported a fatal outcome after taking any of the Covid 19 vaccines to the yellow card system from the start of the roll out until present (Dec 2020 to Sep 2022). Please provide the above information aggregated by month, by age, by vaccine administered; Pfizer, AstraZeneca, Moderna and other.*

2. *I request the total number of individuals from England and Wales who have reported adverse reactions after receiving a Covid 19 vaccine 1,2,3,4,5,6 or 7 doses to the yellow card system from Dec 2020 to Sep 2022. Please provide the above information aggregated by month, by age, by vaccine administered Pfizer, AstraZeneca, Moderna and Other. Also, for the above question if possible could you do three box charts one for non-serious or serious. Please also confirm what qualifies as non-serious or serious.*

3. *What action have you taken in respect of fatal outcomes reported?*

4. *What action have you taken in respect of serious adverse events reported?*

5. *What action does the MHRA take to monitor both fatal outcomes and serous adverse events?*

6. *Being aware of the fact that the East London Coroner issued regulation 28 on 13.10.22 to the secretary of state for health in which a risk of further deaths was highlighted due to the fact that evidence presented to the coroner by a senior medical assessor from your organisation highlighted the fact that full clinical reviews are not possible due to the MHRA being unable to compel the timely production of relevant clinical data. Has there been any changes made to your procedures following the issuing of this regulation 28 and if so, please confirm in detail?*

7. *Given that the above issue has been raised by the coroner who is an independent judicial officer – please confirm how have you undertaken any robust reviews into reported adverse effects and deaths?*

8. *What is your assessment given the number of adverse events and deaths reported to you which are higher than those reported for all vaccinations in the last 30 years.*

9. *Given that the SARS-Cov-2 vaccines were given emergency use authorisation in full knowledge of the fact that they have not undergone full clinical trials – why did the MHRA not feel it was necessary to have a robust operating procedure in place to review adverse events and deaths as a result of these novel vaccines.*

10. *I am also aware that in response to another FOPI request (FOI 22/661) which you issued on 09.06.22 you replied that "you are not able to given information in relation to adverse effects from specific batch numbers as this was not a mandatory field" – I would ask again that given the fact that these drugs have not gone through clinical trials and were under emergency use authorisation why did the MHRS not feel it necessary to mandatorily collect batch numbers for the vaccines.*

11. *Do you have a vaccine recall and protocol procedure?*

12. *We note that the 'age' specific is not mandatory and this was confirmed in FOI (21/1028) issued by you 24.09.21. If you are not collecting age data how can you determine what level of risk the products pose to specific age groups and in particular to children.*

13. *In order to gain true informed consent the recipient needs to be informed of potential adverse effects from any medication that they are to receive. Whilst accepting that at the time of the vaccines being made available to the public the adverse effects information was limited. However, over the period of time of their administration as more information has come to light - what steps have the MHRA undertaken to ensure that information for vaccine recipients has been updated to reflect 'no risks'.*

14. *At the start of the pandemic a number of figures were put out into the public arena by the Imperial College London after they undertook their pandemic modelling. Given that we now have real world data available – has the MHRA requested an update from the relevant organisation(s) as regards any work carried out to revise those initial figures in light of the real-world data we now have? Please provide said data.*

15. *Please provide a copy of your proactive strategy for the continual monitoring of safety of the use of the SARS-CoV-2 vaccines.*

16. *Please provide copies of protocols and procured in place regarding how you work closely with public health partners in reviewing the effectiveness and impact of the vaccines on the public.*

17. *Given that we were facing unprecedented times and that a decision had been made to administer a medicinal product to the general public which had not undergone full trials and therefore, carried a high risk to the recipients - why was a decision not made to make yellow card reporting a mandatory requirement for all health care professionals who had either been involved in the administration of the vaccine or the care of anyone administered and suffered with what could be an adverse effect.*

Please see the information requested below.

Requests 1 and 2

All of the data provided within this response relates to UK spontaneous suspected Adverse Drug Reaction (ADR) reports received directly (not via pharmaceutical companies) from reporters in England and Wales by the MHRA up to and including 23 July 2023. Please note that the accuracy of the data relies on the postcode being provided by the reporter. Where reporters have only provided an email address and not a postal address these reports will not be included in the numbers provided.

Please see attached an Annex including data as per your request:

- Table 1 contains the total number of direct UK spontaneous suspected ADR reports received from England and Wales that report a fatal outcome by initial month received.

- Table 2 contains the total number of direct UK spontaneous suspected ADR reports received from England and Wales that report a fatal outcome by patient age group.

- Table 3 contains the total number of direct UK spontaneous suspected ADR reports received from England and Wales by initial month received.

- Table 4 contains the total number of direct UK spontaneous suspected ADR reports received from England and Wales by patient age group.

- Table 5 provides a breakdown of the total number of direct UK spontaneous suspected ADR reports received from England and Wales broken down by seriousness. A Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, whether the original reporter considers the report to be serious whereby they can select based on 6 criteria[1].

When considering the spontaneous ADR data provided, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the suspect drug or vaccine, only that the reporter had a suspicion it may have been. When any medicine is given to patients, some recipients will inevitably experience illness following its use. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

- Please note that the number of reports provided within this response does not equate to the number of individuals that submitted an ADR report. A single ADR report may be reported from more than one source, and as such, have more than one reporter. When this happens, reports concerning the same patient and adverse drug reaction are merged on our system in to one report.

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[1] The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

Requests 3,4,5,7 and 8

A summary of the MHRA's safety reviews of COVID-19 vaccines including reports with a fatal outcome and other serious events, is available at the following link: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

This report also includes information on how the MHRA monitors reports with a fatal outcome and other events, including serious reports, reported following COVID-19 vaccination.

Request 6

The Regulation 28 report referred to in request 6 was sent to the Rt Hon Therese Coffey, Secretary State for Health and Social Care. The Department of Health and Social Care (DHSC) response to this report did not make any recommendations for changing MHRA protocols and procedures. The DHSC response is available at : https://www.judiciary.uk/wp-content/uploads/2022/10/2022-0316-Response-from-Department-of-Health-and-Social-Care.pdf.

Requests 9 and 15

The MHRA continuously monitors the safety of medicines and vaccines through a variety of robust pharmacovigilance processes including the Yellow Card scheme. For COVID-19 vaccines, the MHRA developed and put in place, a four stranded approach to monitoring their safety (available at: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance).

Request 10

When reporting to the Yellow Card Scheme, patients and healthcare professionals are encouraged to provide as much information as possible, e.g., batch number, patient age, where available. It is not mandatory to provide all this information as this would prevent people from reporting suspected side-effects if not all information is known.

Request 11

Please see the MHRA's guide to defective medicinal products available at A guide to defective medicinal products - GOV.UK (www.gov.uk).

Request 12

Information on age is collected in Yellow Card reports where available however, as outlined in our response to request 10 above, it is not mandatory to provide all this information when submitting a Yellow Card as this would prevent people from reporting suspected side-effects when some information is not known. As detailed in the MHRA Coronavirus vaccine summary of Yellow Card reports (please see response to requests 3,4,5,7 and 8 above), the MHRA closely monitors the safety of COVID-19 vaccine exposures in individuals under 18 years old, including Yellow Card reports for COVID-19 vaccines used in this age group. Additional sources of data are also considered, for example, international experience based on data from other countries using the same vaccines. As discussed in the report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccines safety surveillance (as linked under our response to requests 9 and 15 above), Yellow Card data are intended to flag up potential safety concerns with medicinal products. If a new safety concern is detected, then additional data sources can be used as appropriate to characterise the possible risks (e.g., use of data electronic health records to conduct observational studies).

Request 13

A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information. This information has been kept updated as new information about side effects associated with the vaccines has been identified. Should a new safety issue be confirmed we will continue to act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk and protect public health.

Request 14

The MHRA has not requested an update from Imperial College London regarding their pandemic modelling and therefore we can confirm that we do not hold the information you have requested in relation to request 14.

Request 16

Monitoring the effectiveness of vaccines is the remit of the UKHSA. As such, the MHRA do not hold protocols specifically related to working closely with public health partners to review the impact and effectiveness post-authorisation of the Covid-19 vaccines.

More broadly, there are established ways of working with relevant organisations and expected codes of conduct for government officials.

Request 17

We do not hold information in respect to mandatory reporting of suspected side effects through the Yellow Card Scheme for COVID-19 vaccines however this issue has been considered generally.

The MHRA has reviewed other international mandatory and non-mandatory reporting systems for healthcare professionals and found limited evidence that making reporting mandatory increases the ability to detect safety signals.

In both medicines and devices legislation there are requirements for manufacturers to report, but there is no legal obligation for healthcare organisations. However, there are professional body standards and guidelines that make reporting a gold standard for healthcare professionals. The MHRA continues to work with partners across the healthcare system to promote and encourage use of the Yellow Card scheme to help detect safety issues.

The MHRA has reviewed global approaches to mandatory reporting in other regulatory systems and continues to consider the approach in the UK as we work to improve reporting capability and functionality through systems.

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,

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