Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

16 November 2023

Dear [redacted]

FOI 23/801

Thank you for your Freedom of Information request dated 21 October 2023 which requested the below information:

1) *From 2001 to 2021 in 20 years how many all vaccines was issued and given to public estimated numbers please excluding Covid19 Vaccines from that list please*
2) *How many injuries and death number in them 20 years have all vaccines excluding Covid19 Vaccines from that list have they been in number please this from 2001 to 2021 how many deaths and injuries from vaccines*
3) *From 2021 to 2023 how many suspected injuries and deaths and suspected deaths from all Covid19 Vaccines have the been please in number from all reports and Yellow Cards report*
4) *Has MHRA had a Contract out for AI reporting System in 2020 to monitor high volume of Adverse Reactions from Covid19 Vaccines? And if so what happened to this AI reporting System in link provided is this true https://ted.europa.eu/udl?uri=TED%3ANOTICE%3A506291-2020%3ATEXT%3AEN%3AHTML&fbclid=IwAR2CF1YylyNNGyF9yw1P0shDxPSiXINBV5q2KDySUQKqZLCArdze2td8Y3k*
5) *Did MHRA knew they would be Suspected High Volumes of adverse Reactions before the Roll out of the COVID-19 vaccines would happen like CDC did in they Meeting slide which mentioned all Adverse Reactions in their meeting from pharmaceutical companies did MHRA knew in Advance*
6) *If so, why did MHRA give EUA and Full Authorisations to Pharmaceutical companies Covid19 Vaccines when the condition of Death and Myocarditis and other serious issues was full in Knowledge before the EUA was given isn't this premeditated murder by Pharmaceutical companies and our safety body's authority and government*

Please find our response to each of your questions below:

1) The MHRA do not hold information on the number of vaccines administered within the UK. Whilst we consider vaccine uptake as part of our analysis of the safety of

vaccines, information on the number of individuals administered a given vaccination is not held by the MHRA. This information is held by the UK Health Security Agency (UKHSA), who can be contacted at enquiries@ukhsa.gov.uk.

2) Regarding how many injuries and death have there been for all vaccines, excluding the COVID-19 vaccines, between 2001 and 2021, the MHRA does not hold this information. The MHRA only collects information on *suspected* adverse reactions including those with a fatal outcome to medicines and vaccines. A report of a suspected side effect to the MHRA does not in itself mean that the medicine or vaccination caused the symptom to occur. Only a suspicion is needed to report. The Office for National statistics (ONS) may be able to help further with this aspect of your request. If you would like to obtain further information on how many reports of suspected adverse reactions to vaccinations that the MHRA has received, please submit a new FOI request to MHRACustomerServices@mhra.gov.uk, detailing the specific vaccinations you are interested in.

3) With regards to your third question which asks from 2021 to 2023, how many suspected injuries and suspected deaths from all COVID-19 vaccines have been reported to the Yellow Card scheme, please visit our website where this information is publicly available. The COVID-19 vaccine reports contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. This information does not represent an overview of the potential side effects associated with the vaccines. A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information here.

   Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the reports referenced above alone. When viewing the report, you should remember that:

   - Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.
   - It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.
   - Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
   - It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

4) The MHRA awarded the AI contract in September 2020 with the aim to support processing of suspected ADR reports to COVID-19 vaccines.

   The AI tool has helped us by reducing the amount of manual coding for each report, thereby saving resource in processing cases and ensuring they are rapidly available for scientific analysis. The tool was not used for assessment of data, but to help ensure that all the information provided in narrative text from the reporter was well captured to support analysis. Reports that were processed by the AI are subject to routine review and robust quality assessment and reports are reclassified, if required.

   Throughout the pandemic the MHRA published details of all suspected reactions reported in association with available COVID-19 vaccines, along with our assessment of the data, in our summary of Yellow Card reporting. This includes those processed with support from the AI software.

5) With respect to the anticipated volume of suspected ADR reports for the COVID-19 vaccination programme, this was estimated from a number of previous vaccination campaigns; therefore, we prepared our surveillance systems on this basis. Actual numbers of reports are dependent on various factors including the number of doses administered and use of concurrent treatments. However, we also actively worked across the healthcare sector to increase access to reporting systems during the vaccination campaign and specifically integrated information regarding the reporting of side effects to materials provided at the point of care to people receiving vaccination.

   In addition to social media campaigns, the MHRA issued a Drug Safety Update and a press release informing healthcare professionals and members of the public that reporting to the Coronavirus Yellow Card reporting site will enable the MHRA to rapidly identify new and emerging side effects. The general public were also encouraged to report any suspected side effects to the vaccine to the MHRA via a Yellow Card on the televised press briefings throughout the pandemic. As such, it is not surprising that the MHRA has received a large volume of Yellow Card reports relating to these products.

6) As described in the response to question 5 above, potential volumes of ADRs were estimated based on previous vaccination campaigns. The Covid-19 vaccines were granted Marketing Authorisations following a rigorous assessment and review of their safety, quality and effectiveness. It was concluded that the benefits outweigh any risk. As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored. The benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects in the majority of patients. Patient Information Leaflets (PILs) for all medicines are available to the public online: MHRA Products | Home. The PILs for the COVID-19 vaccines are updated regularly as more information is understood.

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
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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