Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Ms Kathy Gray

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

14th October 2022

Dear Ms Gray

FOI 22/982

Thank you for your FOI request dated 15th September 2022, where you requested reporting figures for the COVID-19 vaccines within Northern Ireland and also details about the MHRA's processes when receiving cases with a fatal outcome and how causality is determined in these reports.

> **1. I am now requesting the total number of individuals from Northern Ireland who have reported a fatal outcome after taking any of the Covid 19 vaccines to the yellow card system showing a NI Post code 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.**

Unfortunately, we have been unable to provide the breakdown (by month, patient age and by vaccine administered) of the Yellow Card reports in part one of your request as this falls under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOIA. As part one of your request relates specifically to fatal reports, this adds an additional layer of information and therefore cumulatively, we believe that there is the potential for patient identification. In addition to this, when broken down in this fashion, there are fewer than 5 reports within each categorisation.

Further to the use of Section 40 and 41, as outlined in our Privacy Policy Privacy Policy | Making medicines and medical devices safer (mhra.gov.uk), the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme. The Policy also states that we may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded.

Where fewer than 5 reports have been received for a specific month, age and vaccination breakdown, we have concealed this number in order to comply with data protection laws and protect reporter confidentiality given the additional factor of geographic breakdown requested. Please note the same applies across the entirety of your request where the number of reports is fewer than 5.

Therefore, in response to part one of your request we have provided the number of fatal reports submitted from Northern Ireland for each COVID-19 vaccine.

September 2022

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Table 1: Number of UK ADR reports from Northern Ireland for the COVID-19 vaccines where there was a fatal outcome

Vaccine	Fatal
COVID-19 Vaccine Pfizer/BioNTech	12
COVID-19 Vaccine AstraZeneca	35
COVID-19 Vaccine Moderna	*
COVID-19 Vaccine Brand Unspecified	0

48 + DEATHS AGE ?

The information supplied in this response relies on the reporter providing a postcode which starts with 'BT' in the original Yellow Card. It has been brought to our attention that a small number of reports were missing from the data we previously provided where the reporter had not provided a complete postcode and as such the reports were not included within the response. This has been rectified such that the current data includes these reports.

Furthermore, if the postcode is incorrectly provided, or if the reporter has provided an email address in place of a postal address, the Yellow Card will not be included in this data. As the data has been extracted using available postal addresses only, it may not reflect the true number of ADR reports following COVID-19 vaccinations reported from Northern Ireland. It is important to note that the number of reports received for Northern Ireland does not directly equate to the number of people who may have experienced adverse reactions and therefore cannot be used to determine the incidence of reactions. ADR reporting rates are influenced by many aspects, including the extent of use.

2. I am now requesting the total number of individuals from Northern Ireland who have reported adverse reactions after receiving a Covid 19 vaccine 1,2,3 or 4 doses to the yellow card system showing a NI Post code 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.
Also for the above question if possible could you do three box charts one for mild, moderate and severe reactions.

Please see Tables 2 – 4 in the attached Excel spreadsheet showing reports from Northern Ireland for each COVID-19 vaccine broken down by month and age group. Please note, upon breakdown of reports received where the brand of vaccine was not specified by the reporter, all categories display fewer than 5 reports. As such we have not provided this in table format, however I can confirm we have a total of 23 reports from Northern Ireland where the brand of COVID-19 vaccine was not specified. Please also note that January to May 2021 are not presented in Table 4 as no Yellow Card reports were received during this time for the Moderna COVID-19 Vaccine.

You have also asked for Box charts for mild, moderate and severe reactions. Yellow Card reports are classified as either non-serious or serious (including fatal). 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]. As we do not hold this data in Box charts we have provided the number of reports from Northern Ireland for COVID-19 vaccines by seriousness up to and including 29th September 2022, in Table 5 attached.

[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.

Please note that cases where an ADR has a fatal outcome are included in the total number of serious cases. Please also note that one report may contain more than one brand of COVID-19 vaccine. For example, someone may report their reactions to both their initial and booster vaccinations within the same report.

3a This leads me to my third question because one paragraph contradicts the other you said fatal outcome does not necessarily mean it has been caused by the vaccine but in the next paragraph you state the MHRA takes all fatal outcomes very seriously and are evaluated and monitored. So which is it?

Both statements are true. A reported suspected adverse event following COVID-19 vaccine does not necessarily mean it was caused by the vaccine. Healthcare professionals and members of the public are asked to report to the Yellow Card scheme even if they have just the slightest suspicion that a medicine or vaccine may have caused a side effect including those with a fatal outcome.

Vaccination and surveillance of large populations means that, by chance, some people will experience and report a new illness or events in the days and weeks after vaccination. A high proportion of people vaccinated early in the vaccination campaign were very elderly, and/or had pre-existing medical conditions. Older age and chronic underlying illnesses make it more likely that coincidental adverse events will occur, especially given the millions of people vaccinated. It is therefore important that we carefully review these reports to distinguish possible side effects from illness that would have occurred irrespective of vaccination.

3b. Is a thorough investigation done in each death to determine the exact cause of death or not?

While each fatal report is evaluated in depth the MHRA do not determine the cause of death and this is instead the responsibility for a Coroner. Coroners are independent judicial officers who investigate deaths reported to them. They will make any necessary inquiries to find out the cause of death, this includes ordering a post-mortem examination, obtaining witness statements and medical records, or holding an inquest. It is not the role of the MHRA to adjudicate on individual events as we assess the body of evidence as a whole.

4a. What investigations are carried out in Northern Ireland and by whom to determine cause of death?
4b. Is the PSNI involved in the investigations with medical staff to determine causation?
4c. Is the Northern Ireland Statistic Research Agency informed and are death certificates rectified once causation is confirmed?

With regards to part 4a of your request please refer to our response to question 3b. For the other parts to question four, unfortunately the MHRA does not hold this information and would suggest these questions are posed to the authorities stated in your request or the Coroner's Office.

5. Copies of MHRA protocols and procedures with respect to Yellow Card reports where a COVID-19 vaccine was the suspect drug and a fatal outcome was reported?

The MHRA does not hold a Standard Operating Procedure which specifically relates to the handling of COVID-19 vaccine Yellow Card reports with a fatal outcome. To be helpful however, we have provided you with a document which describes our signal detection process for all COVID-19 vaccine reports, including those which report a fatal outcome.

I hope the information provided is helpful, but 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.

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Yours sincerely,

FOI Team,
Safety and Surveillance Group

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

Table 5: Number of UK ADR reports from Northern Ireland received for a COVID-19 vaccine by seriousness up to and including 29th Septeml

Vaccine	Non-Serious	Serious (incl. fatal)
COVID-19 Vaccine Pfizer/BioNTech	906	2290
COVID-19 Vaccine AstraZeneca	597	2511
COVID-19 Vaccine Moderna	46	137
COVID-19 Vaccine Brand Unspecified	5	18

1554 4956.

157 86 2597
29 2511
12 2523
146 283 + 18 301
18 23

Total 5444

Together 6510

Table 3: Number of UK ADR reports from Northern Ireland received for the COVID-19 Vaccine AstraZeneca by patient age up to and including 29th Se

Patient Age (Years)	2021											
	January	February	March	April	May	June	July	August	September	October	November	December
0-19	*	*	10	*	*	5	*	*				
20-39	35	71	189	170	254	106	51	26	26	*	6	12
40-59	26	95	266	324	166	102	56	31	36	14	15	11
60-79	8	127	102	79	47	32	14	8	10	5	5	*
80+	24	22	10	26	11	9	*	*	*	*	*	*
Unknown	5	36	83	84	51	48	23	12	10	6	9	

22
2115
444
102
381

3064

ptember 2022.

2022								
January	February	March	April	May	June	July	August	September
*								
6	*	*	*	*	*	*		
7	*	*	*	*		*	*	*
*	*	*	*	*		*		*
7	*	*	*	*	*		*	*

Table 4: Number of UK ADR reports from Northern Ireland received for the COVID-19 Vaccine Moderna by patient age up to and including

Patient Age (Years)	2021											
	June	July	August	September	October	November	December	January	February	March	April	
0-19			*		*	*						4
20-39	*	*	6	12	12	*	11	*		*	*	83
40-59		*	5	*	*	7	10	*	*	*	*	
60-79			*			9	*				*	19
80+											*	9
Unknown	*	*	*	*	6	6	5	*			*	32

Please note that January to May 2021 are not presented in Table 4 as no Yellow Card reports were received during this time for the Moderna COV

147

29th September 2022.

2022				
May	June	July	August	September
*				
		*		*
*		*	*	*
5	*		*	
5	*	*		*
9				

ID-19 Vaccine

Table 2: Number of UK ADR reports from Northern Ireland received for the COVID-19 Vaccine Pfizer/BioNTech by patient age up to and

Patient Age (Years)	2020	2021									
	December	January	February	March	April	May	June	July	August	September	October
0-19	*	*	*	*	8	*	12	5	23	5	7
20-39	23	155	55	115	66	119	138	136	117	70	58
40-59	22	166	58	171	108	112	62	55	26	41	24
60-79	5	18	52	36	35	30	19	11	*	8	7
80+	*	*		*			*				*
Unknown	6	40	20	41	32	42	50	40	29	31	18

117
2301 (2301)
274
9
451

3152

including 29th September 2022.

		2022								
November	December	January	February	March	April	May	June	July	August	September
18	12	11	6	*	*	*	*	*		
46	87	41	17	6	5	*	*	*	*	*
40	83	44	9	6	*		6	*		6
18	13	11	*	*	5	*	*			*
*		*			*	*				
23	41	22	10	*	*	*	*	*		*