



MHRA

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25th May 2023

Dear

FOI 23/310 – Yellow Card reports for Northern Ireland

Thank you for your email dated 27th April 2023, where you asked for information on the following:

From 1/04/2021 to 31/03/2022 and 01/04/2022 to 31/03/2023:

- *Total number of Yellow Card reports submitted from NI for all reporter types*
- *Breakdown of Yellow Card reports from NI by reporter qualification*
- *Breakdown of yellow card reports from NI health trusts/ area*
- *Breakdown of Yellow card reports from NI by non-serious/ serious and fatal reports*
- *Breakdown of patient age from Yellow Card reports*
- *Top 10 suspected medicines from NI Yellow card reports*
- *Top 10 suspected ADRs reported*
- *Source of report*

The MHRA works closely with the UK devolved administrations. All individuals receiving a medicine are encouraged to report side effects to the Yellow Card Scheme by the governments in these territories.

Following a search of our database from the 1st April 2021 up to and including the 31st March 2022, I can confirm that the MHRA have received 4390 spontaneous suspected Adverse Drug Reaction (ADR) reports reported from Northern Ireland over this time period. Further to your request, of these 4390 reports, 30 reports concern a fatal outcome suspected to be associated with the medicine reported.

Following a search of our database from the 1st April 2022 up to and including the 31st March 2023, I can confirm that the MHRA have received 935 spontaneous suspected ADR reports reported from Northern Ireland over this time period. Further to your request, of these 935 reports, 15 reports concern a fatal outcome suspected to be associated with the medicine reported.

The accuracy of this data relies on the postcode being correctly provided by the reporter in the original Yellow Card. Additionally, the provision of postal addresses is not required to submit a report; reporters are required only to provide a contactable address which can be either an email



address or postal address. If reporters only provide an email address, these will not have been included in this analysis.

Please note we are unable to provide data where the number of reports is less than 5 to protect patient and reporter confidentiality and as such disclosing this information is exempt under Section 40 and 41 of the FOIA. Therefore, some of the breakdowns requested in your response have unfortunately not been fulfilled. We have however tried to be helpful and provide data where the restrictions allow or provided slightly less granular information to complete your request. Where there are less than 5 reports, numbers have been replaced with a ^ in the tables below.

Please find below Table 1 which shows the breakdown of reports by age received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively.

Table 1: UK spontaneous suspected ADR reports categorised by age, received between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Age	Number of suspected ADR reports	
	1 st April 2021-31 st March 2022	1 st April 2022-31 st March 2023
0-17	105	61
18-29	582	73
30-39	1,093	106
40-49	909	86
50-59	551	118
60-69	255	113
Over 70	237	123
Unknown	658	255



Please find below Table 2 which show the breakdown of reports by reporter qualification received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively.

Table 2: UK spontaneous suspected ADR reports categorised by reporter qualification, received between 1st April 2021 up to and including 31st March 2022, and between 1st April

Reporter Qualification	Number of suspected ADR reports	
	1 st April 2021-31 st March 2022	1 st April 2022-31 st March 2023
Carer	20	^
Chiroprapist	^	^
Community pharmacist	22	12
Consumer or other non-health professional	187	30
Coroner	^	^
Dentist	13	15
GP	198	30
Healthcare assistant	38	^
Hospital doctor	126	62
Hospital healthcare professional	10	^
Hospital nurse	43	15
Hospital pharmacist	67	59
Medical student	7	^
Midwife	57	^
Nurse	121	47
Optometrist	^	^
Other healthcare professional	81	19
Parent	365	40
Patient	2,798	350
Pharmacist	174	152
Pharmacy assistant	^	^
Physician	17	19
Pre-reg pharmacist	^	38
Radiographer	36	51

2022 up to and including 31st March 2023, from Northern Ireland.



Please find below Table 3 which shows the breakdown of reports by primary care trust received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively. It is important to note when viewing the data for the two time periods below that the rollout of the COVID-19 vaccinations began in December 2020 and continued throughout 2021.

Table 3: UK spontaneous suspected ADR reports categorised by Reporter Primary Care Trust, received between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Reporter Primary Care Trust	Number of suspected ADR reports	
	1 st April 2021-31 st March 2022	1 st April 2022-31 st March 2023
Belfast Commissioning Group	1,131	292
Northern Commissioning Group	914	187
South Eastern Commissioning Group	964	132
Southern Commissioning Group	702	166
Western Commissioning Group	680	169

Please find below Table 4 which shows the breakdown of reports by seriousness, received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively. 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 criteria¹.

Table 4: UK spontaneous suspected ADR reports categorised by seriousness received between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Seriousness	Number of suspected ADR reports	
	1 st April 2021-31 st March 2022	1 st April 2022-31 st March 2023
Non-serious	978	329
Serious (including fatal)	3412	606

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 find below Tables 5 and 6 which show the breakdown of the top 10 suspected medicines present on reports received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively.

Table 5: UK spontaneous suspected ADR reports categorised by the top 10 most commonly reported medicines between 1st April 2021 up to and including 31st March 2022, from Northern Ireland.

Medicine	Number of suspected ADR reports
Tozinameran	2026
Chadox1 ncov-19	1901
Elasomeran	134
Iohexol	28
Influenza virus	24
Sars-cov-2 virus	16
Sotrovimab	15
Adalimumab	9
Ferric derisomaltose	8
Live influenza virus	7

Table 6: UK spontaneous suspected ADR reports categorised by the top 10 most commonly reported medicines between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Medicine	Number of suspected ADR reports
Tozinameran	154
Elasomeran	84
Chadox1 ncov-19	53
Riltozinameran	40
Imelasomeran	27
lomeprol	27
Tezacaftor	21
Ivacaftor	21
Ritonavir	20
Elexacaftor	20



Please find below Tables 7 and 8 which show the breakdown of the top 10 suspected ADRs present on reports received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively.

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 or compare the safety profile of different medicinal products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Table 7: UK spontaneous suspected ADR reports categorised by the top 10 most commonly reported ADRs between 1st April 2021 up to and including 31st March 2022, from Northern Ireland.

Reaction	Number of suspected ADR reports
Headache	844
Fatigue	641
Pyrexia	477
Nausea	415
Chills	340
Pain in extremity	339
Dizziness	291
Myalgia	277
Arthralgia	241
Lymphadenopathy	229

Table 8: UK spontaneous suspected ADR reports categorised by the top 10 most commonly reported ADRs between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Reaction	Number of suspected ADR reports
Fatigue	67
Rash	64
Headache	58
Urticaria	43
Nausea	41
Dyspnoea	38
Covid-19	35
Vomiting	35
Dizziness	31
Pyrexia	31

Please find below Table 9 which shows the breakdown of the source of the report for UK spontaneous suspected ADR reports received from Northern Ireland between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023 respectively.



Table 9: UK spontaneous suspected ADR reports categorised by Source of Report between 1st April 2021 up to and including 31st March 2022, and between 1st April 2022 up to and including 31st March 2023, from Northern Ireland.

Source of report	Number of suspected ADR reports	
	1 st April 2021-31 st March 2022	1 st April 2022-31 st March 2023
Electronic Yellow Card	4,283	886
Clinical System	9	6
Paper	32	12
Other	66	31

This information does not represent an overview of the potential side effects associated with medicines. A list of the recognised adverse effects of specific medicines is provided in the information for healthcare professionals and the recipient information. Conclusions on the safety and risks of medicines cannot be made on the data shown in the report alone. When viewing the data provided, you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.

For a medicine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive medicines without having any serious side effects.

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.

Yours sincerely,

FOI Team,
Safety and Surveillance

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