Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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

www.gov.uk/mhra

30th January 2024

Dear [redacted]

FOI 24/017

Thank you for your response to our clarification request dated 4th January 2024, where you requested the following under the Freedom of Information (FOI) act:

1. *The total number of Yellow Card reports submitted by the University Hospitals of Leicester NHS Trust over a defined time period (January 2021 to December 2023).*
2. *The total number of Yellow Card reports submitted by the University Hospitals of Leicester NHS Trust broken down by reporter qualification for the above period.*
3. *The total number of Yellow Card reports submitted by the University Hospitals of Leicester NHS Trust broken down by reporting route for the above period.*
4. *The total number of Yellow Card reports submitted by the University Hospitals of Leicester NHS Trust broken down by suspect medicine/vaccine reported to have caused the Adverse Drug Reaction (ADR) for the above period.*

You requested the above data to be broken down by individual months. Please note, in order to locate Yellow Card data received from the University Hospitals of Leicester NHS Trust, our search located reports in which the reporter contact details contained one of the below criteria:

- Postcode of LE1 5WW, LE3 9QP or LE5 4PW
- Reporter telephone number contained 0300 303 1573
- Reporter email address contained @UHL-TR.NHS.UK
- Reporter postal address contained Glenfield Hospital, Leicester General, Leicester Royal or University Hospital Leicester

Please note that the information supplied in this response relies on the reporter providing the above information in the contact details of their Yellow Card. If none of the above criteria is met, the Yellow Card will not be included in this data. It is important to note that the number of reports provided in this response 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. Adverse Drug Reaction (ADR) reporting rates are influenced by many aspects, including the extent of use.

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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 does not necessarily mean that the medicine or 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 medicine or vaccine and many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as administration.

Please find attached Annex 1, which provides the requested breakdown of UK spontaneous suspected ADR reports initially received from University Hospitals of Leicester NHS Trust between January 2021 and December 2023. The MHRA are committed to protecting patient/reporter confidentiality, and as such please note that Tables 2-4 have been broken down by initial year of receipt opposed to month/year of receipt in order to provide a more meaningful overview of the data.

Lastly, when the Yellow Card scheme was established, one of the key principles defined was that it would not be used for audit purposes as health professionals should send Yellow Cards on a voluntary basis. Any data provided should not be used in any way to attempt to identify the original reporter of the Yellow Card nor should the data be used for disciplinary or audit purposes.

We 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
Medicines and Healthcare products Regulatory Agency

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Annex 1

Table 1: Number of UK spontaneous suspected ADR reports initially received by the MHRA from University Hospitals of Leicester NHS Trust between January 2021 and December 2023, broken down by month received.

Month and year report was initially received by MHRA	Number of ADR reports
Jan 2021	101
Feb 2021	21
Mar 2021	25
Apr 2021	30
May 2021	25
Jun 2021	32
Jul 2021	19
Aug 2021	16
Sep 2021	7
Oct 2021	7
Nov 2021	8
Dec 2021	10
Jan 2022	4
Feb 2022	4
Mar 2022	1
May 2022	1
Jun 2022	3
Jul 2022	8
Aug 2022	1
Sep 2022	6
Oct 2022	8
Nov 2022	6
Dec 2022	2
Feb 2023	3
Mar 2023	4
Apr 2023	6
May 2023	2
Jun 2023	4
Jul 2023	4
Aug 2023	3
Sep 2023	3
Oct 2023	7
Nov 2023	6
Dec 2023	4

Where zero reports have been received in a month, that month is not included in the table.

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Table 2: Number of UK spontaneous suspected ADR reports initially received by the MHRA from University Hospitals of Leicester NHS Trust between January 2021 and December 2023, broken down by reporter qualification and year received.

Reporter qualification	Year report was received by MHRA		
	2021	2022	2023
DENTIST	2	4	1
GP	1		
HEALTHCARE ASSISTANT	7		
HOSPITAL DOCTOR	101	17	13
HOSPITAL HEALTHCARE PROFESSIONAL	13		
HOSPITAL NURSE	24	1	3
HOSPITAL PHARMACIST	21	2	3
MIDWIFE	6		1
NURSE	21	10	9
OPTOMETRIST	1		
OTHER HEALTHCARE PROFESSIONAL	34	2	1
PARENT	1		
PATIENT	12	1	
PHARMACIST	20	7	9
PHARMACY ASSISTANT	32		6
PHYSICIAN	2		
PRE-REG PHARMACIST	1		
RADIOGRAPHER	4		

Where zero reports have been received, cells have been left blank.

Table 3: Number of UK spontaneous suspected ADR reports initially received by the MHRA from University Hospitals of Leicester NHS Trust between January 2021 and December 2023, broken down by reporting route and year received.

Reporting route	Year report was received by MHRA		
	2021	2022	2023
COVID systems	225	7	
MiDataBank	3	1	
Paper			1
SystmOne		1	2
Yellow Card App			1
Yellow Card website	73	35	42

Where zero reports have been received, cells have been left blank.

Table 4: Number of UK spontaneous suspected ADR reports initially received by the MHRA from University Hospitals of Leicester NHS Trust between January 2021 and December 2023, broken down by suspect medicine/vaccine and year received.

Medicine/vaccine active substance name	Number of ADR reports received by MHRA for suspect medicines/vaccines, by year received		
	2021	2022	2023
ADALIMUMAB	1	0	0
AFLIBERCEPT	0	1	0
ARIPIPRAZOLE	0	0	1
ATOMOXETINE	1	0	0
ATRACURIUM	0	0	1
ATROPINE	0	1	0
BACILLUS CALMETTE GUERIN	0	1	0
BENRALIZUMAB	17	1	3
BICTEGRAVIR AND EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	0	0	1
BORDETELLA PERTUSSIS AND CLOSTRIDIUM TETANI AND CORYNEBACTERIUM DIPHTHERIAE	0	0	1
BUPIVACAINE	1	0	0
CALCIUM AND VITAMIN D3	1	0	0
CAPECITABINE	0	0	1

CARBAMAZEPINE	0	1	0
CARBOPLATIN	1	0	0
COVID-19 Vaccine AstraZeneca	137	0	0
CHLORHEXIDINE	1	0	0
CHLORPHENIRAMINE	1	0	0
CIPROFLOXACIN	0	0	1
CITALOPRAM	1	0	0
CLINDAMYCIN	0	1	0
CO-AMOXICLAV	3	1	0
CO-TRIMOXAZOLE	1	0	0
COBICISTAT AND ELVITEGRAVIR AND EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	2	0	0
CYCLOPENTOLATE	0	0	1
DAPAGLIFLOZIN	2	0	0
DENOSUMAB	0	1	0
DOLUTEGRAVIR AND LAMIVUDINE	0	0	1
DUPILUMAB	0	0	2
COVID-19 Vaccine Moderna	1	0	0
Bivalent COVID-19 Vaccine Moderna	0	5	0
ELEXACAFTOR AND IVACAFTOR AND TEZACAFTOR	4	2	0
ELTROMBOPAG	1	0	0
EMPAGLIFLOZIN	1	0	3
ESTRADIOL	0	1	0
ETHINYLESTRADIOL AND NORELGESTROMIN	1	0	0
FERRIC CARBOXYMALTOSE	1	0	1
FERRIC DERISOMALTOSE	1	0	0
FEXOFENADINE	1	0	0
FIDAXOMICIN	0	0	1
FLOUR MITE AND HOUSE DUST MITE	0	1	1
FLUCLOXACILLIN	1	0	1
GENTAMICIN	1	1	0
HEPATITIS B VIRUS	0	1	2
HUMAN PAPILLOMA VIRUS	0	0	1
IBRUTINIB	1	0	0
IBUPROFEN	0	0	1
IMMUNOGLOBULIN NORMAL	0	1	0
INFLIXIMAB	0	0	1
INSULIN DEGLUDEC	0	1	0
IRON	1	0	0
IVABRADINE	0	0	1
IVACAFTOR	0	2	1
IVACAFTOR AND LUMACAFTOR	0	1	0

IVACAFTOR AND TEZACAFTOR	0	1	1
LANREOTIDE	0	0	2
LANSOPRAZOLE	1	0	1
LEVOFLOXACIN	0	0	1
LISDEXAMFETAMINE	0	0	1
MEPOLIZUMAB	12	2	2
METHOTREXATE	0	0	1
METHYLPHENIDATE	1	0	0
NAPROXEN	1	0	0
NIRMATRELVIR AND RITONAVIR	0	3	1
OMALIZUMAB	1	0	1
ONDANSETRON	1	0	0
PATENT BLUE V	1	0	0
PHLEUM PRATENSE	0	2	0
PONATINIB	0	0	1
PROPOFOL	0	0	1
RAXTOZINAMERAN	0	0	1
REGADENOSON	1	0	0
REMDESIVIR	1	1	0
RIFAMPICIN	0	1	0
ROCURONIUM	1	2	0
ROXADUSTAT	0	1	0
RUCAPARIB	0	1	0
SACUBITRIL/VALSARTAN	1	0	2
Unbranded COVID-19 Vaccine	1	0	0
SEMAGLUTIDE	0	1	0
SERTRALINE	0	1	0
SORAFENIB	1	0	0
SOTROVIMAB	0	2	0
SUGAMMADEX	1	0	0
TECHNETIUM (99M TC) TETROFOSMIN	1	0	0
TEICOPLANIN	1	2	1
TERIFLUNOMIDE	2	0	0
TOCILIZUMAB	1	1	0
COVID-19 Vaccine Pfizer	92	2	0
TRAMETINIB	1	0	0
VALPROIC ACID	1	0	0
VEDOLIZUMAB	0	0	1
VOXELOTOR	0	1	0
WASP VENOM	0	0	1

Please note that a single ADR report may concern multiple suspect medicines/vaccines.