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www.gov.uk/mhra

13 January 2024

Dear

FOI 23/121

Thank you for submitting a refined FOI request dated 3rd April 2023, where you requested **the number** of Yellow Card reports reported annually by members of the public and healthcare professionals from 2010 to the latest year available. Please accept my apologies for the delay in responding to you.

As you may be aware, when submitting a Yellow Card, it is mandatory for healthcare professional reporters to select their healthcare profession from a list of values. The MHRA uses standard qualifications set by The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This list is high level as it is not possible for the MHRA to include every clinical speciality within our drop-down list. Healthcare professional reporters do have the opportunity to provide further information on their speciality within a free text box on submission of a Yellow Card report, however this is not mandatory. As this information is collected in a free text field, entries within that field may vary between reports depending on how a healthcare professional describes themselves.

Please see below Table 1, which includes the total number of UK spontaneous suspected Adverse Drug Reaction (ADR) reports submitted directly to the Yellow Card scheme by members of the public and healthcare professionals by year from 2010 onwards. All of the data provided within this response relates to UK spontaneous suspected ADR reports received directly (not via pharmaceutical companies) by the MHRA. Please note that the reporter qualification categories are available to be selected from our drop-down list. The figure for members of the public contains all reports whereby the reporter selected either patient, parent, carer or consumer/other non-healthcare professional from our qualification drop down list.

When considering the below spontaneous adverse drug reaction (ADR) data, 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.

You will notice that the number of Yellow Card reports received each year increases over time, which is as expected due to increased awareness of the Yellow Card scheme and overall improved reporting functionality.

Furthermore, you will notice that the volume of Yellow Card reports received increases dramatically from 2021 onwards. This is due to the national roll-out of the COVID-19 vaccines and the campaign to encourage individuals to report any suspected side effects to the MHRA. The leaflets provided to UK recipients of the COVID-19 vaccines contain information on how suspected side effects can be reported to the MHRA and encourages reporting of any side effects through the Yellow Card scheme. Information on Yellow Card reporting has been included in NHS training materials, as well as the materials available to individuals both before and after vaccination. As part of MHRA monitoring procedures, we take into account of the variable levels of reporting across all medicines and vaccines using statistical techniques.

I hope that you will find this information useful. If you would like to request this information for a specific substance or group of substances, please submit a new request to MHRACustomerServices@mhra.gov.uk with details of the substances of interest. 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 Group

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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.





Table 1. Total number of direct UK spontaneous ADR reports received by members of the public and healthcare professionals by year from 2010 up to and including 10/04/2023.

	Year													
	Number of Yellow Card Reports													
Reporter Qualification	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023+
Chiropodist	-	-	-	-	-	9	5	-	-	8	7	149	22	-
Community Pharmacist	375	543	978	1059	963	1044	1487	1626	1425	1254	757	1484	306	73
Coroner	12	10	10	5	16	17	6	10	10	31	27	45	19	2
Dentist	32	48	56	54	70	80	64	50	40	49	72	1430	749	190
Healthcare Assistant	#N/A	19	35	38	15	34	30	72	38	81	202	4959	384	21
GP	2611	3466	3643	4366	5024	6308	6287	6678	6370	6731	5351	18249	5847	1379
Hospital Doctor	2101	2239	2144	2384	2278	2406	2445	2468	2294	2365	2094	7828	2158	527
Hospital Healthcare Professional	694	614	445	426	493	570	736	845	833	759	679	1718	451	52
Hospital Nurse	597	726	816	1029	1121	1252	1432	1706	1660	1886	1907	3672	695	149
Hospital Pharmacist	1237	1350	1618	2167	2491	3621	4565	4311	3823	4400	4204	2880	1108	303
Medical Student	-	18	22	25	17	7	10	20	18	27	25	906	54	7
Member of the Public *	2428	2051	2146	3240	4281	5982	7480	8578	9079	9544	9921	362506	55387	7197
Midwife	-	13	21	28	10	23	35	42	50	43	58	667	83	28
Nurse	2704	2134	1702	2127	1922	2350	2732	2892	2535	2202	1918	12110	3283	719





Optometrist	6	11	9	14	18	11	28	19	17	20	19	224	29	9
Other Healthcare Professional	987	902	929	811	659	902	1084	1467	1564	2215	2363	13393	3594	785
Paramedic	-	-	7	7	7	16	18	26	57	47	89	1005	157	26
Pharmacist	448	244	302	355	256	401	662	1205	1378	1524	1573	7051	4686	1820
Pharmacy Assistant	ı	12	29	41	40	69	187	221	521	513	694	1901	776	330
Physician	363	422	322	199	155	191	361	317	172	174	111	2184	2265	897
Pre-Reg Pharmacist	-	125	166	286	322	358	471	579	327	405	498	805	595	200
Radiographer	-	56	93	127	169	209	280	344	348	507	455	1005	761	215

^{*} Members of the public include patients, parents, carers or consumers/other non-healthcare professionals.

^{**} Where less than 5 reports have been received for a given healthcare professional category, these reports have been grouped together to comply with data protection laws and protect reporter confidentiality.

⁺Up to and including 10 April 2023