Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr Ian Dalton
request-784164-e2e41197@whatdotheyknow.com

16/09/2021

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

Dear Mr Dalton,

FOI 21/986 and FOI 21/995

Thank you for your emails dated 22 and 26 August where you requested the following:

- *I would like to know roughly what percentage of the total adverse reactions to vaccines do get reported to you*
- *Total number of vaccine deaths and adverse reactions you have records for the last 20 years*

The Medicines and Healthcare products Regulatory Agency (MHRA) has in place a Yellow Card Strategy to promote the scheme and raise awareness amongst healthcare professionals and patients alike. The reporting rate for spontaneous Adverse Drug Reactions (ADR) is variable and can depend on a multitude of factors. The actual rate is unknown and variable because it is influenced by public awareness and seriousness of the event.

The reporting rate for the COVID-19 vaccines will be increased as in addition to social media campaigns, we have 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. The general public have also been encouraged to report any suspected side effects to the vaccine to the MHRA via a Yellow Card on the televised press briefings. We consider of the variable levels of reporting as part of our monitoring procedures and use statistical analyses which are purposefully designed to minimise the impact of under-reporting.

Please find below Table One showing data for all UK, spontaneous suspected vaccine reports from 01/01/2001 to 05/09/2021 with a data lock point of 08/09/2021. There are columns containing the total number of ADR reports, the total number of reactions and the total number of fatal reports per year. Please note that one ADR report may contain multiple adverse drug reactions. COVID-19 vaccinations have been excluded from this calculation. Information regarding the number of reports for the COVID-19 vaccines can be found in our coronavirus vaccine - weekly summary of Yellow Card reporting.

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

When looking at Yellow Card data it is important to note that a reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the vaccine. 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 drug or vaccine and may be stimulated by promotion and publicity about a drug or 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 above data should not be used as a basis for determining incidence of side effects. During assessment we consider of the variable levels of reporting as part of our monitoring procedures.

Table One: Table showing the total number of ADR reports, total number of reactions and total number of fatal reports for all UK, spontaneous vaccine reports received 01/01/2001-05/09/2021 with a data lock point of 08/09/2021.

Year	Total number of reports	Total number of reactions	Total number of fatal reports
2001	1497	2980	17
2002	1458	2928	17
2003	2147	4340	16
2004	1835	3662	12
2005	2230	4784	14
2006	1513	3839	9
2007	1315	3547	11
2008	2425	5947	21
2009	5429	14708	31
2010	3753	9503	38
2011	2507	6970	24
2012	1875	6048	15
2013	2899	9328	24
2014	2733	8596	20
2015	3079	10440	26
2016	3394	11053	22
2017	3880	12326	19
2018	3926	12968	25
2019	3360	11215	23
2020	2737	9060	13
01/01/2021-05/09/2021	2959	10337	6

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,

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

FOI Team,
Vigilance and Risk Management of Medicines Division

The MHRA information supplied in response to your request is subject to Crown copyright. The FOIA only entitles you to access to MHRA information.

For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information

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