Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

20th March 2024

Dear [redacted]

FOI 24/228
FOI 24/229

Thank you for your Freedom of Information (FOI) request dated 5 March 2024 in which you requested the below information concerning pregabalin.

1. *How many deaths (total numbers per year) have there been annually from 2013 to 2023?*
2. *How many deaths (numbers as a percentage of total prescriptions) have been there annually from 2013 to 2023?*
3. *What are the demographics for deaths from this drug per year from 2013-2023?*
4. *Where do these deaths rate against deaths by other drugs in the top 5 drugs contributing to deaths annually for 2013-2023?*
5. *When were safety concerns first raised with MHRA?*
6. *What is/are the cause/s of death?*

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals. There is also a legal obligation for pharmaceutical companies to report to us.

Whilst anyone can report their suspicions of a safety concern or incident, 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 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 particular side effect or outcome.

For points 1, 3, 4 and 6 of your request, the MHRA does not hold information on the number of patients that have pregabalin listed as a cause of death on their death certificate, as this falls outside of our remit. The MHRA do not determine causality of individual reports, and this includes reports of fatalities. You may wish to contact the Office for National Statistics (ONS) here FOI.Team@ons.gov.uk as they may hold this information.

Additionally, the MHRA does not hold the information in point 2 of your request. Whilst the MHRA consider the usage of particular medicines as part of our ongoing safety analysis, we do not hold information on the number of prescriptions given for a particular medicine. This information is held by the UK Health Security Agency (UKHSA). UKHSA are a public authority under the FOIA and you may wish to direct a request for this information to them at - InformationRights@UKHSA.gov.uk

In accordance with Section 16 of the FOIA, concerning the provision of advice and assistance to those requesting information under FOI we have provided some further information below which you may find useful.

Whilst we cannot give certified side effects and deaths, we do hold information around suspected side effects that have been reported to us via the Yellow Card scheme, which are publicly available and can be found on our website via our interactive Drug Analysis Profile (iDAP) for pregabalin.

Additionally, to provide assistance for point 4 of your request, please see the below Table 1 which shows the five most frequently reported drug substances that report a fatal outcome in the spontaneous suspected ADR reports received by the MHRA. To note, pregabalin falls outside of the 20 most frequently reported drug substances that report a fatal outcome.

Table 1: Number of UK spontaneous suspected ADR reports for the five most frequently reported drug substances that report a fatal outcome as of 6 March 2024

Drug Substance	Number of ADR reports
CLOZAPINE	7114[1]
CHADOX1 NCOV-19	1459
TOZINAMERAN	914
RANIBIZUMAB	869
PREDNISOLONE	673

Finally, in reference to point 5 of your request, regarding when safety concerns were first raised with the MHRA, the first UK spontaneous suspected ADR report for pregabalin was received on 21 December 2004. The product information for each medicine outlines what is known about the medicine, including possible safety concerns and is updated as new information becomes available. The product information consists of the Summary of Product Characteristics which is intended for healthcare professionals and the Patient Information Leaflet which is supplied with each pack of medicine. Copies of these documents can be accessed online at the MHRA's website. In addition, healthcare professionals are informed about new or updates on existing safety concerns through our bulletin Drug Safety Update.

[1] Clozapine has additional requirements for regular blood tests which are managed through Patient Monitoring Services. As a result of having these patient monitoring schemes in place, suspected adverse reactions are detected and reported through the Yellow Card Scheme more frequently than for other medicines not subject to mandatory patient monitoring schemes. This extensive monitoring of clozapine means that the MHRA also receives all reports where the patient has sadly died because of events occurring alongside, but not necessarily causally related to, their clozapine use.

Recently articles have been issued on the risk of severe respiratory depression (February 2021) and the safety of pregabalin in pregnancy (April 2022).

As mentioned earlier in our response, when considering the above information, it is important to note that an ADR report is not proof of a side effect occurring but a suspicion by the reporter that the drug may have caused the side effect. The fact that symptoms occur after a drug is given does not mean that they are caused by the drug itself as underlying or undiagnosed illnesses and other factors may be responsible. Furthermore, the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions to drugs for a number of reasons. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug or vaccine and promotion and publicity about a drug or vaccine.

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

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