Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

23rd February 2024

FOI 24/088

Dear [redacted]

Thank you for your information request, dated 27 January 2024, where you requested:

"*I would like to make a freedom of information (FOI) request to receive MHRA data of all complications and adverse events of Hyaluronidase use reported in the UK. Dates included: from 1st January 1999 to 1st January 2024 to cover a 25 year period.*

Please also kindly include the following information with all complications/adverse events reported:
1) Patient details including: Age, Gender, Weight, Height, Ethnicity
2) Suspected drug: Brand, Dosage, Source, Reason for taking the medicine, where the medicine was obtained
3) Suspected reaction details: Reaction, Side effects, Date, Outcome of each reaction, if reaction was serious and how severely was the patient affected by the reaction, sequence of events, and also whether reaction occurred as a result of a mistake made in the prescription, dosing, dispensing or administration of the medication
4) Additional details: other medicines taken, medical history, other information that me be important, including any other medical condition, any allergies, or the results of any tests performed.
5) Source of report - Member of Public, Healthcare Professional, Professional details".

In response to your request, I can confirm that we do hold this information however most of the information is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available and can be found here: https://yellowcard.mhra.gov.uk/idaps. Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for a specific substance. This includes all reports received

from healthcare professionals, members of the public, and pharmaceutical companies. The filters on the left-hand side of the page can be used to select a subset of reports such as age (10 year bands), sex, route of administration, report seriousness, year received, and source of report. Included within the iDAPs are reports of adverse events which constitute mistakes made in the prescription, dosing, dispensing or administration of the medication.

This information does not represent an overview of the potential side effects. As you will know, a list of the recognised adverse effects is provided in the information for healthcare professionals and the recipient information MHRA Products | Home.

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

Many of the additional fields listed in your request which are not otherwise published under iDAPs, would have to be provided in a format that would be listed by each individual report we hold. We cannot provide all this information at the level of individual reports as this cumulative information could identify the patient or reporter. As such this is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the Freedom of Information Act.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request and provide clarification on the exact information you wish to receive. For example, listed below are the fields we could provide you with as standalone information or as separate aggregated tables if this would be helpful:

- Patient weight
- Patient height
- Patient ethnicity
- Brand of suspect drug
- Reason for taking the medicine
- Reporter qualification

Please be advised however that many of these fields are optional when submitting a Yellow Card report and as such are not always provided. If you are interested in particular adverse reactions, we could also provide data on the number of those reactions with specific outcomes reported. Similarly, we can provide information on the number of reports which include particular medical history you are interested in.

I hope the information provided both here and in the iDAPs is helpful, however if you are interested in receiving any additional information outlined in the options above please let us know by return of this email. 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

Please remember to quote the reference number above in any future communications.

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:

Information Commissioner's Office
Wycliffe House
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