Medicines & Healthcare products
Regulatory Agency

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[redacted]

17 April 2024

FOI 24/267

Dear [redacted],

Thank you for your information request, dated 17 March 2024, where you requested the following:

1. Of these reported adverse events for Hyaluronidase, in how many cases was Hyaluronidase suspected (or proven) as the sole drug cause of the adverse event?

2. Of these reported adverse events, is it possible to know what doses of Hyaluronidase was used?

3. Can you provide information on the number of reports which include patient medical history of allergy (e.g. allergy to bees, wasps, medications etc)?

4a: Standalone information or separate aggregated tables for brand of suspect drug Hyaluronidase

4b: Standalone information or separate aggregated tables for reason for taking the medicine Hyaluronidase

4c: Standalone information or separate aggregated tables for reporter qualification

5. I note in your letter, you state “If you are interested in particular adverse reactions, we could also provide data on the number of those reactions with specific outcomes reported.” I would ask for further data for the following particular adverse reactions please: localised skin reactions, immediate skin reactions, delayed skin reactions, anaphylaxis, infection, and neuromuscular symptoms (spasm, stiffness, weakness, and pain). These may include but not limited to erythema, eczema, haematoma, bruising, or contusion, rash, oedema, cellulitis, spasm, stiffness, weakness, and pain.

I can confirm the MHRA does hold the information you have requested, as such this has been detailed below for you.

1. The MHRA has received 128 UK spontaneous suspected adverse drug reaction (ADR) reports for hyaluronidase up to and including 20 March 2024. Of these reports,

96 are for hyaluronidase where it is the only suspect drug reported. These data includes both single and multi-constituent products.

2. Table 1 in the attachment provides details on the dose of hyaluronidase, where reported within the 96 reports. Please note that it is not mandatory to provide dose details when submitting a Yellow Card report. Furthermore, one report may contain more than one dose entry.

It is important to note that the dose information reported for drug substances will vary depending on several factors including the specific product in the case, indication and route of administration.

3. A total of 9 ADR reports out of the 128 contain information regarding a patient medical history of allergy. The reported medical history reaction terms include, drug hypersensitivity, dermatitis contact, food allergy, milk allergy, drug hypersensitivity, seasonal allergy, allergy to metals and rubber sensitivity.

4a to 4c - Tables 2 to 4 attached show the drug name, indication and reporter qualification included in the 128 ADR reports where hyaluronidase is reported as a suspect drug, either alone or as a co-suspect drug. Please note that it is not mandatory to provide the drug indication when submitting a Yellow Card report. Furthermore, a single report may have more than one reporter.

5. The MHRA uses the Medical Dictionary for regulatory Activities (MedDRA) to code adverse drug reactions in our database. The 'System Organ Class' (SOC) (the highest level in MedDRA) groups together reactions that affect similar system/organ in the body. The preferred term (PT) is the most specific reaction term and is used for coding ADR reports. The following MedDRA SOC and PTs were used to conduct this data extraction based on your request: Infections SOC, PTs including skin reactions, anaphylactic reaction, muscle spasms, musculoskeletal stiffness, muscular weakness, pain, erythema, eczema, haematoma, contusion, rash, rash erythematous, oedema, cellulitis.

Table 5 in the attachment shows the total number of reports for each PT as above, and the outcome as provided at the time of reporting

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

When considering the spontaneous data provided, it is important to be aware of the following points:

- A reported reaction **does not** necessarily mean it has been caused by the vaccine, medicine, or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine, or device, 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 or compare the safety profile of different vaccines, medicines, or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

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,

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
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