Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

5th December 2023

Dear [redacted]

FOI 23/865: UK Yellow Card reports for hyaluronidase since 2000

Thank you for your email dated 9 November 2023, where you asked for information on the following:

All UK Yellow Card reports for hyaluronidase since 2000, specifically including:
The indication for use of hyaluronidase

- *The location of the body in which hyaluronidase was used*
- *The nature of the complication (type of reaction/ area of the body affected/ did the resolution resolve/ length of time to resolution/ any treatment required for complication)*
- *Time between administration and adverse reaction*
- *The age and gender of the patient suffering the reaction (and if possible details regarding their comorbidities)*
- *Prescriber background (ie doctor/ non-medical)*
- *Setting in which hyaluronidase was used (eg medical clinic/ aesthetic clinic etc).*

Unfortunately, we are unable to provide all UK Yellow Card reports relating to hyaluronidase as this information is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient or reporter identification.

Section 40 protects personal data, the disclosure of which would breach one or more of the data protection principles. The Agency is satisfied that disclosure here would breach the first data protection principle, in particular the requirement of fairness on the basis that disclosure would not be reasonably expected by the people mentioned in the information. Section 41 states that information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

However, some of the information you have requested is already publicly available in a format which protects patient and reporter confidentiality. Please allow us to direct you to interactive Drug Analysis Profiles (iDAPs) that provide a complete listing of all suspected adverse reactions reported to the MHRA

via the Yellow Card scheme for medicines and COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. You can navigate across iDAPs by searching for the active ingredient of the product, which in this case would be hyaluronidase. Filters on the left-hand side of the iDAP will also allow you to filter for the number of reports based on multiple parameters including patient sex, patient age, reporter qualification, year received, route of administration and nature of the reaction.

If you still wish to obtain further information that is not already available publicly, you can request data under the FOI Act for which we will be able to provide you with summary tables for the data within Yellow Cards that we do hold. I would like to note that we do not hold information regarding prescriber background or setting in which hyaluronidase was used.

It is 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. Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse reaction. The existence of an adverse drug reaction (ADR) report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.

It is also important to note that reported adverse reactions have not been proven to be related to the drug and should not be interpreted as a list of known side effects. For a list of the known, possible side effects and the frequency please refer to the Patient Information Leaflet (PIL) or the Summary of medicinal Products Characteristics (SmPC) for healthcare professionals. These documents can be accessed on the MHRA website (http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/) which is available to all patients, doctors and pharmacists.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision. 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

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