Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

26th June 2023

Dear [redacted]

FOI 23/396

Thank you for your Freedom of Information request dated 26th May 2023, where you requested:

Safety information/Yellow Card Data for Licensed allergan Immunotherapies listed below:

1. *Grazax*
2. *Acarizax*
3. *Pollinex*
4. *Itulazax*

Further to your request please find attached Product Analysis Prints (PAP) which list all the spontaneously reported Adverse Drug Reaction (ADR) reports received up to and including 06/06/2023 associated with Grazax, Acarizax, and Pollinex. Please note a PAP has not been provided for Itulazax, as we've received 2 ADR reports associated with this product. Where we have 5 or less reports to maintain patient confidentiality under Section 40 of the FOIA (personal information), we cannot disclose further information.

Please find enclosed a guidance sheet which provides you with further information on how to interpret the print.

When considering spontaneous ADR data, it's important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine or medicine, 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. We continuously review Yellow Card reports, alongside all other sources of safety data, to monitor safety and identify any new risks.

- 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 products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

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I hope the information provided is helpful; however, 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 & Surveillance Group

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