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[redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: Sunday, March 24, 2024 12:09 PM
To: [redacted]
Subject: FOI 24/235 Omalizumab

You don't often get email from [redacted]

FOI 24/235

Dear [redacted]

Thank you for your Freedom of Information Act request which we received on the 5 March 2024.

Your request and our response

Regarding your Freedom of Information (FOI) request on the use of omalizumab in adults and certain children to reduce the severity of allergic reactions, please see below a list of granted marketing authorisations for Xolair (omalizumab) products:

- **Xolair 150 mg powder and solvent for solution for injection (PLGB 00101/1170)**
- **Xolair 150 mg solution for injection in pre-filled syringe (PLGB 00101/1171)**
- **Xolair 75 mg powder and solvent for solution for injection (PLGB 00101/1172)**
- **Xolair 75 mg solution for injection in pre-filled syringe (PLGB 00101/1173)**
- **Xolair 300mg solution for injection in pre-filled syringe (PLGB 00101/1219)**
- **Xolair 300mg solution for injection in pre-filled pen (PLGB 00101/1220)**
- **Xolair 150mg solution for injection in pre-filled pen (PLGB 00101/1221)**
- **Xolair 75mg solution for injection in pre-filled pen (PLGB 00101/1222)**

Our response

I can confirm that MHRA holds this information.

Xolair is currently authorised for the following indications:

Allergic asthma

Xolair is indicated in adults, adolescents and children (6 to <12 years of age). Xolair treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe CRSwNP for whom therapy with INC does not provide adequate disease control.

Chronic spontaneous urticaria (CSU)

Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

Further information on Xolair is available through the Summaries of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) and Public Assessment Report (PARs) published on the MHRA website. A link to this information is provided below:

https://products.mhra.gov.uk/search/?search=Xolair&page=1

If you have a query about the information provided, please reply to 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 you receive this response and addressed to: info@mhra.gov.uk

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

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely,

HQA FOI team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Tuesday, March 5, 2024 8:49 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/235 Omalizumab

Good evening.

Given the recent approval by the FDA for the use of Omalizumab in adults and certain children, to reduce the severity of allergic reactions, I would like to know if the MHRA has considered the possibility of that medication also being approved in England for the same purposes.

Kind regards,

[redacted]

[redacted]

[redacted]