

FW: FOI 23/1013 - RE: Black Triangle Medication

Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>

Wed 24/01/2024 14:05

To: MHRAs Customer Services <MHRACustomerServices@mhra.gov.uk> [REDACTED]

1 attachments (192 KB)

Black Triangle List.pdf;

Hi Both,

For your records.

Many thanks,

From: Pharmacovigilanceser

Sent: Wednesday, January 24, 2024 2:05 PM

To: [REDACTED]

Subject: FOI 23/1013 - RE: Black Triangle Medication

Dear [REDACTED]

FOI 23/1013

Thank you of your email dated 29/12/2023, where you requested:

1. A **list of Black Triangle drugs and vaccines** currently authorised for use in the United Kingdom, and
2. Details of the **criteria used** by MHRA when deciding to remove the Black Triangle classification for new drugs and vaccines: when the safety of the drug or vaccine has been well-established and additional monitoring is no longer required.

In response to your request, please find attached the current Black Triangle list. Medicines will be typically assigned a Black Triangle for a period of five years. Medicines may continue to have a Black Triangle if this is requested by regulators taking into account the time needed to complete the obligations placed on a medicine marketing authorisation. A medicine previously removed from the list may be reinstated if new conditions related to monitoring of risks and benefits of a medicine are imposed after the granting of the marketing authorisation.

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 & Surveillance Group

Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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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

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From: [REDACTED]
Sent: Friday, December 29, 2023 8:28 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 23/1013 - Black Triangle Medication

Freedom of Information Team
Medicines and Healthcare Products Regulatory Agency [M H R A]
10 South Colonnade
Canary Wharf
London
E14 4PU

My Ref: [REDACTED]
Your Ref:
Date: 29 December 2023

Dear Freedom of Information Team

Subject: Black Triangle Medication

A Black Triangle symbol is assigned to any drug or vaccine if it meets any of the criteria which is:

- a new active substance or a biosimilar medicine
- a new combination of medicines or active substances
- a new route of administration
- a new drug-delivery system
- an established medicine which is to be used in a new patient population

I would be grateful if you could arrange to provide me - from MHRA records - with the following information.

1. A list of **Black Triangle drugs and vaccines** currently authorised for use in the United Kingdom, and
2. Details of the **criteria used** by MHRA when deciding to remove the Black Triangle classification for new drugs and vaccines: when the safety of the drug or vaccine has been well-established and additional monitoring is no longer required.

I look forward to receiving the information at your convenience. Thank you.

Yours sincerely

[REDACTED]
[REDACTED]

[REDACTED]

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