FOI 24/129 - FOI Request

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Wed 06/03/2024 16:58

To [redacted]

FOI 24/129

Dear [redacted]

Thank you for your request of 7 February 2024 where you asked:

> *"!My request concerns the product Abrysvo (RSVpreF): Marketing Authorisation Number PLGB 00057/1722*
>
> *The marketing authorisation includes the indication "passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy".*
>
> *No lower age limit is specified for maternal immunisation.*
>
> *The sponsor is currently undertaking a clinical trial in the USA of the same product RSVpreF in children aged 2-18.*
>
> *"Picasso" NCT05900154, C3671016, EudraCT Number 2022-503134-32*
>
> *1. Does the MHRA marketing authorisation include authorisation for adolescent (under 18) pregnant people?*
>
> *2. Would the MHRA expect to be notified (either by the sponsor or a regulatory authority) of a clinical trial involving an MHRA approved product in participants in the age range covered by their marketing authorisation?*
>
> *3. Is the MHRA aware of this trial? https://clinicaltrials.gov/study/NCT05900154*
>
> *4. Would the MHRA expect to be notified of serious adverse events occurring in this trial of an MHRA approved product?*
>
> *5. Is the MHRA aware of any adverse events occurring in this trial?*
>
> *6. If so, how could I find out more about these adverse events from the MHRA?"*

We have processed your request under the Freedom of Information Act and provide our responses below.

1. *Does the MHRA marketing authorisation include authorisation for adolescent (under 18) pregnant people?*

   There is no lower age limit on maternal immunisation during pregnancy.

2. *Would the MHRA expect to be notified (either by the sponsor or a regulatory authority) of a clinical trial involving an MHRA approved product in participants in the age range covered by their marketing authorisation?*

   MHRA would not expect to be informed of a clinical study that is not being conducted in UK sites.

3. *Is the MHRA aware of this trial? https://clinicaltrials.gov/study/NCT05900154*

   Please see our response to Question 2, above

4. *Would the MHRA expect to be notified of serious adverse events occurring in this trial of an MHRA approved product?*

5. *Is the MHRA aware of any adverse events occurring in this trial?*

6. *If so, how could I find out more about these adverse events from the MHRA?*

For questions 4, 5 and 6, we can advise that The MHRA does not hold records of serious adverse events occurring in trials that

have not been approved in the UK.

To assist, the current adverse events profile for this product is available from the Summary of Product

Characteristics, a link to this is provided below:

https://mhraproducts4853.blob.core.windows.net/docs/80a3ef928288c4d31cea1f8e2c1bdbcdd7245c6a

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely,

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Wednesday, February 7, 2024 9:14 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI Request

Dear Sir or Madam

I am writing to you under the Freedom of Information Act 2000 to request the following information from the Medicines & Healthcare products Regulatory Agency (MHRA).

My request concerns the product Abrysvo (RSVpreF): Marketing Authorisation Number PLGB 00057/1722

The marketing authorisation includes the indication “passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy”.

No lower age limit is specified for maternal immunisation.

The sponsor is currently undertaking a clinical trial in the USA of the same product RSVpreF in children aged 2-18.

"Picasso" NCT05900154, C3671016, EudraCT Number 2022-503134-32