Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2024/00368**

27 August 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 31 July. You wrote:

> *Dear Sir/Madam, Can you advise where I can search of gain access to any reports submitted on Ashwagandha (Withania somnifera (L.) Dunal). Regards* [redacted]

MHRA Response

We confirm that we hold the information you have requested. The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals.

Following a search of our database, I can confirm that the MHRA have received a total of 35 UK spontaneous suspected Adverse Drug Reaction (ADR) reports through the Yellow Card scheme reporting the substance withania as the suspect drug.

Please find attached a Drug Analysis Print (DAP) for the substance withania. The print contains information on all the reports received through the Yellow Card scheme reporting the substance withania. Please note that ashwaganda is a synonym for withania somnifera and as such, any reports reporting this term will be included within the data provided. The attached DAP guidance sheet provides you with further information on how to interpret the print.

Conclusions on the safety and risks of the medicinal products cannot be made on the data shown in the DAP. When considering the attached spontaneous data, it is 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. Each year, millions of doses of drugs are given in the UK alone, and when any drug is used by large numbers of people, some recipients will inevitably experience illness following treatment. The fact that symptoms occur after use of a drug or vaccine, 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.

- 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 drugs. 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 drugs during the first one to two years on the market and then falls over time.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information