Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2024/00811**

23 January 2025

Dear [redacted],

Thank you for your Freedom of Information (FoI) request received on 20 December. You wrote:

I would like to make a request for the following information.

- This notice was published this week https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fadvertising-investigations-november-2024%2Ffcfb0961-d088-4697-b29d-229c460e864b&data=05%7C02%7Cfoi.request%40mhra.gov.uk%7C21e18c34cebc465b44c408dd211d6168%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638703133246385389%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C80000%7C%7C%7C&sdata=sgQzNzsCsE27zmze39jpbQvxOVHAK8odErrxbfLnr1s%3D&reserved=0. I would like a breakdown of all complaints received against Releaf, including how many in total and what the complaint was.
- I would like any communication between the MHRA and Releaf.
-I would like a breakdown of yellow card reports for all medicinal cannabis products for 2024,2023,2022, 2021, 2020. I would like the total number of complaints and a breakdown of what condition was reported in each instance.

MHRA Response

Firstly, please note that the response to your FOI request is due today 23 January 2025. We received your request on the 20 December 2024 and an acknowledgement was sent which stated that we will respond to your request by the 23 January 2025. Four bank holidays have occurred during this time period (UK and devolved nations) and as such today is the 20th working day since you initially sent in your request; we apologise for any confusion this may have caused.

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach

one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Under the FoI Act, MHRA is not obliged to confirm or deny that it holds personal information about third parties, but in any event, even if was held, the Agency would not disclose personal information to you concerning any complaints received associated with Releaf and any subsequent correspondence between the MHRA and Releaf.

Additionally, we are also engaging an exemption from disclosure under Section 41(1) of the FoI Act, which protects information provided in confidence.

The information you have requested relates to complaints received associated with Releaf which was obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

However further to the last point of your request I can confirm we do hold this information.

It may be helpful to firstly provide some background information to allow interpretation of this data. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.

Cannabis sativa is the botanical name for a species of cannabis plant used for recreational and medical purposes. There are three licensed products which contain cannabidiol (CBD) which is an active substance within Cannabis sativa, these are Sativex, Epidyolex, and Nabilone. However, there are no authorised medicinal products in the UK which consist of Cannabis sativa plant material.

The Yellow Card scheme captures information about products that contain cannabis sativa and cannabidiol or a combination of these substances, including illicit and unlicensed products. We have extracted information from our database relating to products containing the substance ‘cannabis sativa’. Cannabis based products containing cannabidiol have not been included in

this response, but details of the adverse reactions suspected to be associated with these products are available on the MHRA website[1].

The Yellow Card scheme has received a total of 98 UK spontaneous suspected ADR reports associated with Cannabis sativa between 1st January 2020 and 31st December 2024, which are displayed by year in table 1 below.

Table 1: Number of UK spontaneous ADR reports between 01/01/2020 – 31/12/2024 associated with Cannabis sativa

Year	Total number of ADR reports
2020	7
2021	12
2022	32
2023	24
2024	23
Total	98

When considering the spontaneous ADR data detailed above, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or medicinal product, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the product. Underlying or concurrent ill-nesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

Further to your request, please find attached Drug Analysis Print (DAPs) for Cannabis sativa. This DAP contains complete data for all UK spontaneous suspected adverse reactions, reported between 1st January 2020 and 31st December 2024. Please refer to the attached information sheet for guidelines on how to interpret the DAP.

The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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

Yours sincerely,

MHRA Central Freedom of Information Team

[1] https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000434008988.zip&agency=MHRA

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
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