Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2024/00809**

23 January 2025

Dear [redacted],

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

> *I've come across two reported incidents within the healthcare organisation I work for regarding Bunov, buprenorphine 5 microgram patches and coming of the patients, possibly due to the adhesive. has there been many reports submitted for this issue, batch 426868 and Exp date: 08/2025*

MHRA Response

We confirm that we hold the information you have requested.

Following a search of our database up to and including 22/01/2025, I can confirm that we have not received any reports for Bunov alongside a product quality issue related to adhesion. Additionally, none of the reports we have received associated with Bunov include the batch number batch number 426868.

Please note that batch number and dosage are not always reported since these fields are not mandatory on a Yellow Card reporting form. Currently from the data we hold there is no evidence to suggest an issue with these particular patches. However, we would be grateful if you could report the cases via the Yellow Card Website, and include the batch number where possible. Once received, they will enter our routine review for further assessment. The MHRA continuously monitors the safety of all 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 assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

I hope the information provided is helpful. 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.

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