Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00554**

15 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 19 May. You wrote:

> *I am writing as a follow-up to my Freedom of Information request (Ref: FOI2026/00368), responded to on 24 April 2026. This request is being made under the guidance of* [redacted]
>
> *Following your advice, I have reviewed the publicly available iDAP for levobupivacaine. Having filtered the data to adults (aged 19 and over) and to the epidural route of administration specifically, I can confirm the following from the iDAP:*
>
> * *Total epidural reports (adults): 32*
> * *All 32 reports fall under a single System Organ Class: Injury, poisoning and procedural complications*
>
> * *Within these, 7 reports relate to anaesthetic and allied procedural complications, including cardiac and neurological events consistent with Local Anaesthetic Systemic Toxicity*
>
> *While this confirms the MHRA holds clinically relevant data, the publicly available iDAP does not provide the granular detail required for the pharmacokinetic safety analysis that the doctoral research protocol demands. Specifically, given that approximately 8% of Yellow Card reports capture dosage information and approximately 12% capture infusion duration, the publicly accessible dataset is insufficient to determine whether adverse events were associated with doses approaching or exceeding the 400mg/24h SmPC limit.*
>
> *I am therefore formally requesting access to Category Ib data fields (as detailed in Annex C of the Access to Yellow Card Data Guidance Notes) for all spontaneous ADR reports where levobupivacaine was administered via the epidural route in adult patients (aged 18 and over).*
>
> *The specific data fields I am requesting are:*
>
> * *Patient age category*
> * *Patient sex*
> * *Dose of suspect drug (mg)*
> * *Route of administration (confirmed as epidural)*
> * *Duration of treatment/infusion*

* *Time to onset of reaction*
* *Suspected adverse drug reaction(s) at MedDRA Preferred Term level*
* *Adverse drug reaction outcome(s)*
* *Indication for use (to isolate post-operative cases)*
* *Year of receipt*

I acknowledge that any data subset containing fewer than five cases per cell will be aggregated prior to release in line with MHRA policy, and I am content to proceed on that basis.
Where possible, I would be grateful to receive the data in a machine-readable format (e.g., .csv or Excel) to facilitate analysis.
This data will be used solely for the purpose of doctoral research protocol development. All data will be held securely and confidentially in line with the Data Protection Act 2018.

MHRA Response

We confirm that we hold the information you have requested.

In response to your request, I can confirm that the MHRA has received a total of 33 UK spontaneous adverse drug reaction (ADR) Yellow Card reports associated with levobupivacaine, where levobupivacaine was reported as having been administered via the epidural route in patients aged 18 years or over, up to and including 11th June 2026.

Please note that the Yellow Card database is dynamic, and therefore the number of reports may change over time as new reports are received or follow-up information is submitted. The Interactive Drug Analysis Profile (iDAP) runs up to the date specified on the iDAP itself, which should be considered the relevant data lock point for that output.

Please see Tables 1, 2a and 2b attached, which provide the data requested. Table 1 outlines the information available for each report, including the dose of the suspect drug, route of administration, duration of suspect drug treatment, time to onset of the reaction(s), suspect adverse drug reaction(s) at MedDRA Preferred Term level, adverse drug reaction outcome(s), indication for use of the suspect drug, and the year in which the report was received.

Tables 2a and 2b provide aggregated demographic information for the identified reports. Table 2a shows the number of reports broken down by patient age category, while Table 2b shows the number of reports broken down by patient sex.

Tables 1, 2a and 2b have been provided in both CSV and PDF formats. This is to ensure that the information is presented clearly and that the report details in Table 1 can be clearly attributed to the relevant individual case.

When considering the below and attached spontaneous ADR data, 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 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 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. 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.

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 assessed and cumulative information reviewed at regular intervals. Medicines and vaccines encompass a wide variety of products with different indications, different ingredients and different mechanisms of action and as such safety for each product is considered individually rather than as a group.

It is very important that this information is not interpreted as a list of possible side effects, nor should these data to be used to estimate the frequency of side effects. For a list of the known, possible side effects and the frequency please refer to the Patient Information Leaflet (PIL) or the Summary of medicinal Products Characteristics (SmPC) for healthcare professionals. These documents can be accessed on the MHRA website (http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/) which is available to all patients, doctors and pharmacists.

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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