Medicines & Healthcare products
Regulatory Agency

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[redacted]

22nd March 2024

Dear [redacted]

MHRA Refs: FOI 24/173 and FOI 24/200

Thank you for your Freedom of Information requests dated Tuesday 20th February 2024 and Tuesday 27th February 2024 where you requested details of Yellow Card reports related to defective long-acting olanzapine and aripiprazole injections that staff from Tees, Esk & Wear Valleys NHS Trust have reported, within the last two years.

In order to address your request, we have widened our search criteria for any UK spontaneous suspected Adverse Drug Reaction (ADR) reports where olanzapine or aripiprazole are included as a suspect drug, specifically where the drug formulation is injection, and the reporter postal code matches any of those previously provided (detailed in Table 1), received from 01/01/2022 to date.

Table 1: Postcodes within the Tees, Esk & Wear Valleys NHS Trust

Tees, Esk & Wear Valleys NHS Trust		
DH1 4LW	HG4 1HZ	YO8 9BX
DH1 5RD	HG5 0UB	YO11 3EG
DH3 3JX	SR8 3DY	YO12 6DN
DH3 3UR	TS1 3LF	YO12 7SN
DH8 0NB	TS4 2PX	YO17 7JP
DL2 2TS	TS4 3AF	YO17 7NG
DL6 1JG	TS6 0NP	YO21 1JH
DL14 6AE	TS10 5RS	YO24 4EY
DL14 6SA	TS18 3TX	YO24 4LJ
DL14 6QN	TS19 0EA	YO31 8TA
DL16 6JF	TS24 7DX	YO32 9XW
HG1 2PW	TS25 1NN	

Following our search, I can confirm that we were unable to locate any UK spontaneous suspected ADR reports matching the above-mentioned criteria. It is important to note that reporter postal code is an optional field when completing a Yellow Card, so reporters may have only provided details such as email addresses when submitting a report. Furthermore, suspect drug formulation is also a non-essential field. Therefore, the true number of reports received could be higher.

Furthermore, I can confirm that we have not received any defective medicine reports regarding olanzapine or aripiprazole injections from Tees, Esk & Wear Valleys NHS Trust since 01/01/2022. Please also be assured that the MHRA have not detected any defect signals in relation to olanzapine or aripiprazole injections requiring regulatory action.

Please also note the following considerations in relation to the above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- Use of our Yellow Card scheme by the healthcare sector and members of the public is voluntary and it does not provide absolute adverse incident figures.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.

Support like yours is invaluable in helping us to continuously monitor the safety of medicines and published information about known side effects which allows patients and healthcare professionals to make informed decisions. We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

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