Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

20 March 2024

FOI 24/186

Dear [redacted]

Thank you for your information request, dated 23 February 2024, where you asked for:

- *"…minutes of the meeting your MHRA safety monitoring team produced in relation to this enquiry"* (related to CEC 154615 health risk of excess zinc query)

We can confirm that there are no minutes in relation to this enquiry. Our procedures for handling potential signals were described in the initial correspondence dated 25 August 2023. However, we hope that the information provided below in relation to your specific enquiry will help to enhance your understanding of our procedures.

To clarify, your enquiry on the potential signal related to the risk of copper metabolism disorders with use of zinc products were reviewed against current Yellow Card reports, the current licensed product information from the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), in addition to published scientific literature and data from case reports. This information was presented at the signal meeting dated 24 August 2023 and was discussed within our team of multidisciplinary specialists, with representatives from different medical backgrounds and professions including scientists, physicians and pharmacists.

As per the information provided to you in the initial correspondence, there was a consensus at the meeting that the risk of copper deficiency is sufficiently highlighted in the product information and the balance of benefits versus risks of oral zinc products remain favourable at present, and so no additional measures were required at the time. The minutes of the

signal meeting are recorded when it is agreed that a signal is identified that may require regulatory action and subsequent communication to patients and healthcare professionals or a signal that has been evaluated is considered closed. However, as it was agreed that no further action was warranted at the time, minutes were not recorded in relation to this signal.

Every Yellow Card report is reviewed as it is received with weekly signal detection meetings. Although full narrative minutes are not recorded, comments are assigned to each drug event combination for audit purposes.

If you have a query about the information provided, please reply to this email.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Benefit Risk Evaluation