

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

20th November 2023

Dear

## FOI 23/827 - REF NatPSA/2003/010/MHRA

Thank you for your updated Freedom of Information request dated 26<sup>th</sup> October 2023, where you specified the exact information, you required following our response to FOI 23/715. In your latest request you asked:

• The information I am looking for has no bearing on the individual or manufacture, what I was trying to ascertain was where did these incidents occur for example: Acute services, community services, nursing or residential services also what type of rails where in use if any, was it the correct rails, was any accessories in use.

It is important to note that information on where the incidents occurred is not routinely collected via Yellow Card reports and as such is not always provided by the reporter. Further to your request, I can confirm that of the 72 reports stated in FOI 23/715, 14 occurred within a hospital setting, 7 were at home and 4 occurred within residential settings. The remaining 47 reports contained insufficient information relating to where the incident occurred. Additionally, for these 72 reports no information was provided by the reporter, relating to whether the correct rails or accessories were used.

Please note, the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. Additionally, the figures provided above are not the same as complication rates.

I 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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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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

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