Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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London
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www.gov.uk/mhra

18 March 2024

Dear [redacted],

FOI 24/169

Thank you for your initial email dated 20 February 2024, where you requested further details of 26 reports that the Medicines Information Team at Northwick Park Hospital identified of loperamide in association with cardiac events between 01 January 2017 and 31 December 2023. You requested information about the loperamide dose, frequency, indication for use, and if the patient(s) had a full bowel anatomy.

Following your request, we conducted a search of our Adverse Drug Reaction (ADR) database for all UK spontaneous suspected reports of loperamide and a reaction in the Cardiac Disorders System Organ Class (SOC), initially received between 01 January 2017 and 31 December 2023. This search returned 16 ADR reports containing a total of 25 ADRs in the Cardiac Disorders SOC.

Please find attached Annex 1, which provides the requested breakdown by dose, frequency, indication for use, and past medical history for each of the 16 UK spontaneous suspected ADR reports. Please note that it is not mandatory to report the dose, frequency, indication of a medication when submitting a Yellow Card report, nor is it mandatory to submit information on the past medical history of the patient. Therefore, this information is not available for all 16 reports on our system.

When the Yellow Card scheme was established, one of the key principles defined was that it would not be used for audit purposes as health professionals should send Yellow Cards on a voluntary basis. Any data provided should not be used in any way to attempt to identify the original reporter of the Yellow Card nor should the data be used for disciplinary or audit purposes.

It is important to note that the number of reports provided in this response does not directly equate to the number of people who may have experienced adverse reactions and therefore cannot be used to determine the incidence of reactions. ADR reporting rates are influenced by many aspects, including the extent of use.

Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine or vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the medicine or vaccine has caused the reaction. It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction.

Sometimes reactions can be part of the condition being treated rather than being caused by the medicine or vaccine and many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as administration.

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,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency