Medicines & Healthcare products
Regulatory Agency

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[redacted]

24 August 2023

FOI 23/577

Dear [redacted]

Thank you for your information request, dated 3 August 2023, where you requested: *"Whether there is any evidence of allergy to ezetimibe in patients with known allergy to beta lactam antibiotics. Are you able to provide me with data on reported allergy to ezetimibe?"*

As per your request, I can confirm that the MHRA have received 13 spontaneous suspected UK Adverse Drug Reaction (ADR) reports with ezetimibe (single constituent) as the suspect drug where the patient experienced an allergy-related ADR as defined by the HLGT "Allergic conditions" within MedDRA[1]. These reports were then further reviewed to determine whether the patient had a reported known allergy to beta lactam antibiotics. Upon review it was found that none of the 13 cases reported a known allergy to beta lactam antibiotics. Please note however, that a patient's past medical and drug history is not a mandatory field and therefore is not always provided. Consequently, there may be some patients who experienced an allergic reaction in association with ezetimibe that had a previously known allergy to beta lactams but due to a lack of information we cannot determine this.

As you will be aware, when considering the provided 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 drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. 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, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls

[1] MedDRA (Medical Dictionary for Regulatory Activities) is a clinically validated international medical terminology dictionary. It's organised by System Organ Class (SOC), divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and finally into Lowest Level Terms (LLT).

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over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

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 individually assessed and cumulative information reviewed at regular intervals. Any emerging evidence relating to possible risks associated with vaccines and medicines, is carefully reviewed and, if appropriate, regulatory action would be taken if any serious risks were confirmed.

If you plan on sharing or publishing the data within this response more widely, please provide us with a copy beforehand so we can ensure correct interpretation.

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.

Yours sincerely,

FOI Team,
Safety and Surveillance