FOI 23/163 Emerade adrenaline autoinjector

REQUEST

28 February 2023

With regard to the **Emerade adrenaline autoinjector,** from the time of its registration/launch in 2014 through to its recent market reintroduction in Oct 2021 (post recall in early 2020), could you tell me if the MHRA has ever received any reports from the marketing authorisation holder (Bausch & Lomb) or any other (previous) MAH, or any complaints from patients or member of the medical or pharmaceutical profession, regarding **problems or difficulties with opening or accessing the outer plastic packaging/tube.**

If so, could you disclose the details of any such report and any consequent changes to the design of the outer packaging, notified to the MHRA by the MAH.

This request is made under the Freedom of Information Act 2000.

MHRA RESPONSE

28th March 2023

Dear

Thank you for your Freedom of Information request dated 28th February 2023, where you requested data on any “problems or difficulties with opening or accessing the outer plastic packaging/tube” of the Emerade adrenaline autoinjectors.

The MHRA have received 2 reports regarding problems or difficulties with opening or accessing the outer plastic packaging/tube. The first report was received in October 2016, and the second report was received in June 2017. During the investigations, the Marketing Authorisation Holder (MAH) informed the MHRA that they had received ‘ten cases thus far from the date of launch in the UK for “outer casing difficult to open” - 2014 to June 2017; however, these were not received by the MHRA directly. The MAH implemented a change to Emerade outer casing in January 2016. In relation to the case notified in October 2016, the MAH noted that there are no deviations or other notations in the batch records that indicate any problem that might be related to this complaint. With regard to the case received in June 2017, the complaint sample was received and tested. The MAH stated that for both reports, the sample was received. The MAH confirmed that the sample ‘was easy to open’ without any force, and it was indicated that the user had tried to ‘twist the cap since the outer label was wrinkled. Both complaints were considered as handling errors, and the MHRA took no further action at the time.

When considering this spontaneous data, it is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who experience adverse reactions or product quality issues and, therefore, cannot be used to determine the incidence of a reaction or product quality issue. Reporting rates are influenced by the seriousness of the reported adverse reaction, their ease of recognition, the extent of use of a particular medicine, 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 over time.

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,
FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency