Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
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09 August 2023

Dear [redacted]

FOI 23/537

Thank you for submitting an FOI request dated 25th July 2023, where you requested the following information:

"We would like to make a Freedom of Information request for the MHRA to provide us with the statistics surrounding the number of reports and the reason for the reports for EllaOne or Ulipristal acetate used for emergency contraception purposes and any potential or actual harm to the user caused by Ellaone.

We are interested in any potential link between EllaOne and those reporting Liver damage or toxicity following the use of Ulipristal acetate and if this was a single use or the patient had used multiple doses over a period of time"

I can confirm that the MHRA has received 584 UK spontaneous suspected ADR reports concerning EllaOne or ulipristal acetate used for emergency contraception purposes up to and including 28th July 2023. A full list of reported adverse reactions within these reports is provided in the attached Drug Analysis Print (DAP). For reports where the reporter did not specify the suspect medication to be EllaOne, reports of ulipristal acetate whereby the indication was stated to be emergency contraception or the dose administered was 30mg have been included.

Please refer to the enclosed information sheet for guidelines on how to interpret the DAP. In addition, when considering the attached spontaneous adverse drug reaction (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 suspect drug or vaccine, only that the reporter had a suspicion it may have been. When any medicine is given to patients, some recipients will inevitably experience illness following its use. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. 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 vaccine, and may be stimulated by promotion and publicity about a vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

You asked specifically about reports of liver damage or toxicity. None of the 584 reports concerned reactions within the Hepatic Disorders System Organ Class (SOC). As you may be aware, the MHRA considered the risks of liver damage or toxicity in reviews in 2018 and 2020 in conjunction with the European Medicines Agency. These found cases of serious liver injury when ulipristal acetate 5 mg (Esmya and generic medicines) was used to treat or control symptoms of uterine fibroids. However, the reviews found no concern had been raised about liver injury with single-dose emergency contraception medicines containing ulipristal acetate.

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 Group