Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11 March 2024

Dear [redacted]

FOI 24/146

Thank you for your email dated 12 February 2024, where you requested:

We have a query about the incidence of pulmonary embolisms (PE's) in Medroxyprogesterone use. Do you have any data regarding the percentage of PE's reported for users/timescale of them developing from start of use?

Further to your request for incidence of pulmonary embolism, unfortunately we do not hold this information as neither the total number of reactions occurring, nor the number of patients using the drug is known, therefore incidence cannot be determined from our Yellow Card reports. Whilst we consider usage data as part of our analysis of the safety of medicines, information on the number of prescriptions is not held by the MHRA. This information is held by the UK Health Security Agency (UKHSA).

However, you may be interested to review our interactive Drug Analysis Profiles (iDAPs) for medicines on our website which list all the spontaneous reported adverse reactions for each drug substance. Up to and including 28 February 2024, the MHRA has received a total of 52 UK spontaneous suspected Adverse Drug Reaction (ADR) reports of medroxyprogesterone associated with pulmonary embolism. Of these 52 reports, only 15 cases reported a time to onset, which included a varied range of timescales with the minimum time to onset being one day and the longest time to onset being 744 days. A further breakdown can be found in the table below.

Table 1: The number of UK spontaneous suspected ADR reports of Medroxyprogesterone and pulmonary embolism which include a time to onset, up to and including 28 February 2024.

Time to onset	Number of reports
0 to 14 days	6
15 to 30 days	1
31 to 60 days	1
61 to 90 days	2
91 to 120 days	1
121 to 250 days	0
251 + days	4

When considering the above spontaneous ADR data, it is important to be aware of the following points:

- The inclusion of a particular reaction on our system does not necessarily mean that it has been caused by the suspect drug. Many factors must be considered in assessing causal relationships, including temporal association, the possible contribution of concomitant medication, and the underlying disease. We encourage reporters to report suspected ADRs i.e., the reporter does not have to be sure of a causal association between the drug and the reactions – a suspicion will suffice.
- As stated earlier in the response, the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions to drugs for several reasons. 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 over time.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects of each medicine.

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,
Vigilance and Risk Management of Medicines Division