Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

17th April 2023

Our Ref: FOI 23/231

Dear [redacted]

Thank you for your Freedom of Information request dated 28th March 2023, where you requested MHRA data of the number of fatal cases received where misoprostol is indicated for abortion, since 01/01/2020.

Further to your request, I can confirm that the MHRA have not received any UK spontaneous suspected adverse drug reaction (ADR) reports concerning misoprostol, where it is indicated for abortion and includes a fatal outcome, from 01/01/2020 to present. However, please be aware that suspect drug indication is not a compulsory field when completing a Yellow Card report, so this may not have been reported in certain cases. Therefore, the number of reports received could be greater than zero.

I also feel it may be beneficial to direct you to our interactive Drug Analysis Profiles (iDAPs), which list all UK suspected spontaneous reactions reported for a medicine or vaccine via the Yellow Card scheme. The filters on the left-hand side of the page can be used to select a subset of reports including seriousness and year received. However, this data cannot be filtered by suspect drug indication.

For ease of reference, please see the iDAP for misoprostol using the following link:
https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000562107006.zip&agency=MHRA

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

I hope the information provided is helpful. 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

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF