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

15 April 2024

Dear [redacted],

RE: FOI 24/273

Thank you for your information request, dated 19 March 2024, where you asked for the below information on Fostair inhaler devices in the same manner as was provided in FOI 24/164.

"I was wondering whether there was any chance you could help me further by providing exactly the same information (particularly the Product Analysis Print (PAP) report) for the equivalent Fostair inhaler devices i.e.:

Fostair 200micrograms/dose / 6micrograms/dose inhaler ([redacted]
Fostair 100micrograms/dose / 6micrograms/dose inhaler ([redacted]

We are trying to determine if there is any apparent difference between these products (Luforbec & Fostair, the pMDI[redacted]) inhaler device forms) in terms of adverse effects, particularly frequency of cough (plus other respiratory adverse effects). Any help you can provide (at your earliest convenience if possible) would be very much appreciated."

I am pleased to confirm that as of 19 March 2024, the MHRA has received 1,524 UK spontaneous suspected Adverse Drug Reaction (ADR) reports concerning Fostair. Please find attached a Product Analysis Print (PAP) which contains a breakdown of all reported reactions and refer to the enclosed information sheet for guidelines on how to interpret the PAP. Please also see Table 1 and Table 2 which provide a further breakdown by patient age and patient sex. Unfortunately, due to the way medicines and vaccines are structured in our system we are unable to separate the two forms of Fostair and as such the data includes reports of both the pressurised inhalation solution and the inhalation powder.

In your request you mentioned that you wished to use the provided data to compare Luforbec and Fostair, therefore when considering the provided 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 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 enclosed data should not be used as a basis for determining incidence of side effects.

- It is not possible to compare the safety of different products by comparing the numbers presented in the reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

Table 1: All UK spontaneous suspected ADR reports concerning Fostair up to and including 19 March 2024, broken down by patient age group

Patient Age Group (Years)	Total Number of ADR Reports
0-9	1
10-19	17
20-29	98
30-39	125
40-49	188
50-59	213
60-69	265
70-79	241
80-89	70
90-99	5
Unknown	301

Table 2: All UK spontaneous suspected ADR reports concerning Fostair up to and including 19 March 2024, broken down by patient sex

Patient Sex	Total Number of ADR Reports

Female	1049
Male	424
Unknown	51

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

If you have a query about the information provided, please reply to this email

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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