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 March 2024

Dear [redacted]

FOI 24/164

Thank you for your Freedom of Information (FOI) request dated 19 February 2024 where you asked for all Yellow Card Reports associated with Luforbec, which had been submitted to the MHRA since the launch date of Luforbec to the present (current date). You noted that if it was not possible to have access to the full Yellow Card Reports, that you would like to request details of the reason that the Yellow Cards were submitted; for example, any information reported on adverse drug reactions/side effects associated with these particular inhalers and further details on the patients involved.

Release of full Yellow Card reports are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the Freedom of Information Act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

However, I can confirm that as of 6 March 2024, the MHRA has received 270 UK spontaneous suspected Yellow Card reports concerning Luforbec. Please find attached a Product Analysis Print (PAP) which contains a breakdown of all UK spontaneous suspected Adverse Drug Reactions (ADRs) reported within these reports. Please also see Table 1 and Table 2 which provide a further breakdown by patient age and patient sex.

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Table 1: All UK spontaneous suspected ADR reports concerning Luforbec up to and including 6 March 2024, broken down by patient age group

Patient Age Group (years)	Total number of ADR reports
0-9	1
10-19	0
20-29	7
30-39	22
40-49	24
50-59	35
60-69	33
70-79	19
80-89	14
90-99	1
Unknown	114

Table 2: All UK spontaneous suspected ADR reports concerning Luforbec up to and including 6 March 2024, broken down by patient sex

Patient Sex	Total number of ADR reports
Female	184
Male	62
Unknown	24

When considering the spontaneous ADR data provided within this response, 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.

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

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