

Request: 20 February 2023

Product: Ciclesonide (Alvesco) - Inhalation aerosol for the treatment of asthma - PL 52811/0007 (80mcg) and PL 52811/0008 (160 mcg)

We write with a request for information under the Freedom of Information Act 2000 in respect of any generic or hybrid marketing authorisation applications identifying the above product as the reference medicinal product.

Please would you provide the following details in respect of any such generic or hybrid marketing authorisation applications:

- date of filing
- applicant's name
- strengths, dosages and indications (label)
- basis of those applications (e.g. whether they are based on *in vitro* and/or *in vivo* studies)
- procedure being used
- status and progress, including any reasons for delays.

MHRA response: 26 March 2023

Regarding applications received by MHRA, we would refuse to confirm or deny under Section 41 (S41) and Section 43 (S43) of the FOI Act (FOIA).

S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a competitor is close to obtaining a marketing authorisation or not.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

Yours sincerely

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

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