

FOI 24/199 FOI Request Azelastine nasal spray (1996)

**F** FOILicensing

To: [REDACTED]

Tue 26/03/2024 10:21

**FOI 24/199**

Dear [REDACTED]

Thank you for your communication, dated 27 February 2024, where you requested the following:

***'Please could I request a copy of the final public consultation for Azelastine nasal spray (1996), reclassification of legal status from POM to P'.***

**Our response:**

Rhinolast (azelastine hydrochloride) Nasal spray (PL 08336/0039) was granted a Marketing Authorisation to Asta Medica Limited on 20 November 1990, as a prescription only medicine (POM). Subsequently, a Marketing Authorisation was granted for Rhinolast (azelastine hydrochloride) Allergy Nasal Spray (PL 08336/0060) to Asta Medica Limited on 07 August 1996, as a Pharmacy Medicine (P). The Marketing Authorisation for the P product was granted via an informed consent procedure, cross referring to the POM product.

Unfortunately, our historical records show that we do not hold a copy of a final public consultation for Azelastine nasal spray (1996), reclassification of legal status from POM to P. We do however hold the following documents, with regards to the Marketing Authorisation application for Rhinolast Allergy Nasal Spray (PL 08336/0060) which you may be interested in:

- a Committee on safety of Medicines (CSM) committee paper, which was reviewed at the CSM meeting on 26 October 1995 and contains the assessment of the change from POM to P
- a company expert report, dated 26 June 1995, containing supporting evidence on the legal status change from POM to P

If you would like to view these documents, you can do so by sending a new FOI request.

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 email: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

After that, if you remain dissatisfied, you may write to the Information Commissioner at;  
The Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,

FOI Team

**From:** [REDACTED]**Sent:** Tuesday, February 27, 2024 11:14 AM**To:** MHRA Customer Services <[MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)>**Subject:** FOI 24/199 FOI Request Azelastine nasal spray (1996)

Dear MHRA

Please could I request a copy of the final public consultation for Azelastine nasal spray (1996), reclassification of legal status from POM to P.

Many thanks

[REDACTED]