Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2026/00993**
FOI2026/01016

14 September 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) requests received on 07 and 09 September 2026.

For FOI2026/00993 you wrote:

I am writing to submit a Freedom of Information request concerning the following medicinal product:

- *Product: Glycopyrronium Bromide 1 mg/5 ml Oral Solution*
- *PL number: PL 13606/0339*
- *Marketing Authorisation Holder: Strides Pharma UK Ltd.*

Having reviewed the MHRA Public Assessment Report (PAR) for this product, I understand that the marketing authorisation application was submitted under an applicable Regulation 10.1 procedure and that a biowaiver was relied upon in support of the application.

I would be grateful if the MHRA could provide, under the Freedom of Information Act 2000, a copy of the redacted biowaiver justification/documentation submitted in support of the application for PL 13606/0339.

In particular, I would like to request:

1. The biowaiver justification submitted by the applicant.

2. Any supporting scientific/technical documentation relating to the justification for the biowaiver.

I understand that certain information may be exempt from disclosure under the Freedom of Information Act 2000. Where this is the case, I would appreciate the MHRA identifying the relevant exemption(s) relied upon and providing the non-exempt portions of the requested documents.

For FOI2026/01016 you wrote:

Dear MHRA,

I am reviewing the Summary of Product Characteristics (SmPC) for Alimemazine Tartrate 7.5 mg/5 ml Syrup (PL 17780/0465), for which Zentiva Pharma UK Limited is the Marketing Authorisation Holder.

I note that sodium sulphite anhydrous (E221) and sodium metabisulphite (E223) are included under the section "Excipients with known effect", while L(+) ascorbic acid is listed in the full list of excipients in Section 6.1.

Could you please confirm the function/role of the following excipients in this medicinal product:

Sodium sulphite anhydrous (E221)

Sodium metabisulphite (E223)
L(+) ascorbic acid

MHRA Response
Under Section 14(1) of the FOI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious, if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether an FOI request(s) is vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious for the following reasons:
We are already working on an FOI request for you (FOI2026/00936), which is currently requiring consultation with a third party (the marketing authorisation holder). To also work on FOI2026/00993 and FOI2026/01016 for you also, both of which will require consideration of documents, redactions under the FOI Act and consultation with different third parties (i.e. different marketing authorisation holders), would bring a total of three requests for information on three different marketing authorisations that require consultation with three separate marketing authorisation holders.

We estimate that the work itemised above would place a disproportionate burden on staff in order to meet your aggregated requests in their entirety. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOIA applies on this occasion.

We ask if you can please wait until we have responded to your first FOI request (FOI2026/00936) before submitting any further requests. As we have stated, this is currently going through third-party consultation, and we are waiting to see if they raise any objections to the release of the requested information.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/