Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

16 November 2023

Dear [redacted]

FOI 23/791 and 23/799

Thank you for your FOI requests dated 19 October 2023, where you requested various forms of information regarding the safety and regulatory compliance of parties involved in various aspects of the manufacture and distribution of certain products.

The requests
23/791
The following documents relating to the pharmaceutical product known as "Carbamyl Glutamic Acid Powder for Oral Liquid" (or sometimes "Carglumic Acid") which is or has been the subject of Wholesaler Distribution Licence number WDA(H) 16788 (the "Product" and the "Distribution Licence"):
1.1 a copy of the Distribution Licence;
1.2 copies of all manufacturing and distribution licences relating to the Product, including any Manufacturing Specials Licence issued to (i) Thorpe Laboratories Limited, (ii) Dechra Limited and/or
(iii) Surepharm Services Ltd (or any entities with similar names) (the "Manufacturers");
1.3 all documents recording communications between the MHRA (including the DMRC) and any of the Manufacturers regarding the Product, including (i) copies of all correspondence and (ii) any notes of any conversations;
1.4 all documents recording communications between the MHRA (including the DMRC) and any holder of any other licence relating to the Product (including with the holder of the Distribution Licence, Veriton Pharma Ltd) regarding the Product, including (i) copies of all correspondence and (ii) any notes of any conversations; and
1.5 any documents recording communications between the MHRA (including the DMRC) and any third party regarding (i) the safety of the Product or of any batch of the Product or (ii) regulatory compliance of any party involved in the manufacture, distribution or dispensing of the Product or any ingredient of the Product – in each case, including all correspondence and any notes of any conversations.

23/799

The following documents relating to:
1.1 Epistatus (10mg in 1ml) maleate base (licenced)
Name on MHRA website: Epistatus 10mg Oromusosal Solution (Midazolam (as maleate))
Product type: Single dose pack (one-pre filled syringe)
Licence Number: PL 16786/0003
1.2 Epistatus (10mg in 1ml) maleate base (unlicensed)
Product Type:
(a) Multi-dose 5ml bottle (Bottle Product); and
(b) Products containing a pre-filled syringe or multiple pre-filled syringes – available in 2.5mg, 5mg, 7.5mg and 10mg (Lower Dose Syringes).
(together the "Product")
2 The documents requested are:
2.1 All documents recording communications between the MHRA (including the DMRC) and Torbay Pharmaceuticals Limited / Veriton Pharma Ltd (or any entities with similar names) regarding issues with the Bottle Product, including unsecured / loose bottle top / cap issues. Please include i) copies of all correspondence; and ii) any notes of any conversations.
2.2 All documents recording communications on or after 18 May 2020 between the MHRA (including the DMRC) and Veriton Pharma Ltd / Plas-Tech Engineering Inc / Torbay Pharmaceuticals (or any entities with similar names) regarding any safety or regulatory issue including without limitation:
2.2.1 Product vacuum leak tests (including the results of such tests) or any other discussion of or information on leakage issues relating to the Product;
2.2.2 issues with Product syringe(s);
2.2.3 Product component issues; and / or
2.2.4 putting the manufacture of the Product on hold and / or quarantining Products including i) copies of all correspondence; and ii) any notes of any conversations.
2.3 any documents created on or after 18 May 2020 recording communications between the MHRA (including the DMRC) and any other third party regarding i) the safety of the Product or of any batch of the Product or ii) regulatory compliance of any party involved in the manufacture, distribution or dispensing of the Product or any ingredient of the Product – in each case, including all correspondence and any notes of any conversations.
2.4 All documents recording communications regarding the licencing of (or unlicensed status of) any other dose of midazolam, including but not limited to Lower Dose Syringes

Our response

Having reviewed each of your requests, we estimate that compliance with each of these would exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000.

There is also a further reason why we consider that section 12 applies. This is section 12(4)(d) which with the 'Fees Regulations 2004' says:

Freedom of Information Act 2000 12
Exemption where cost of compliance exceeds appropriate limit. (4)The Minister for the Cabinet Office may by regulations provide that, in such circumstances as may be prescribed, where two or more requests for information are made to a public authority—(a)by one person, or (b)by different persons who appear to the public authority to be acting in concert

or in pursuance of a campaign, the estimated cost of complying with any of the requests is to be taken to be the estimated total cost of complying with all of them.

The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004
Estimating the cost of complying with a request – aggregation of related requests 5.—(1) In circumstances in which this regulation applies, where two or more requests for information to which section 1(1) of the 2000 Act would, apart from the appropriate limit, to any extent apply, are made to a public authority— (a)by one person, or (b)by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign, the estimated cost of complying with any of the requests is to be taken to be the total costs which may be taken into account by the authority, under regulation 4, of complying with all of them. (2) This regulation applies in circumstances in which– (a)the two or more requests referred to in paragraph (1) relate, to any extent, to the same or similar information, and (b)those requests are received by the public authority within any period of sixty consecutive working days.

Although we consider that the time needed to retrieve the information for each request alone would exceed 24 hours, we also consider that these two requests should be aggregated. The requests were received on the same day and cover the same over-arching theme of safety and regulatory compliance of parties involved in manufacture and distribution.

We have determined that the time taken for the following activities will exceed the cost limit:
- determining whether we hold the information;
- finding the requested information, or records containing the information;
- retrieving the information or records; and
- extracting the requested information from records.

This is because for 23/791, your request in its present form covers:
- all documents recording communications between the MHRA (including the DMRC) and any of the Manufacturers regarding the Product
- documents recording communications between the MHRA (including the DMRC) and any holder of any other licence relating to the Product
- any documents recording communications between the MHRA (including the DMRC) and any third party regarding (i) the safety of the Product or of any batch of the Product or (ii) regulatory compliance of any party involved in the manufacture, distribution or dispensing of the Product or any ingredient of the Product

And for 23/799, your request in its present form covers:
- One licenced and five unlicenced products
- All documents recording communications between the MHRA (including the DMRC) and Torbay Pharmaceuticals Limited / Veriton Pharma Ltd (or any entities with similar names) regarding issues with the Bottle Product
- All documents recording communications on or after 18 May 2020 between the MHRA (including the DMRC) and Veriton Pharma Ltd / Plas-Tech Engineering Inc / Torbay Pharmaceuticals (or any entities with similar names) regarding any safety or regulatory issue
- any documents created on or after 18 May 2020 recording communications between the MHRA (including the DMRC) and any other third party regarding i) the safety of the Product or of any batch of the Product or ii) regulatory compliance of any party

involved in the manufacture, distribution or dispensing of the Product or any ingredient of the Product
- All documents recording communications regarding the licencing of (or unlicensed status of) any other dose of midazolam

In order to determine if the information that you have requested is held, and to retrieve any such information, we would have to search email accounts and SharePoint files of a large number of MHRA staff members that may have been involved in communicating with any of the parties (manufacturers/licence holders/any third parties) that you have stated. This includes staff members that work in Standards and Compliance, Process Licensing, Product Licensing, DMRC, Safety and Surveillance and the Customer Experience Centre. This would involve extensive IT searches to locate any potentially relevant information and then a manual review of the items that are found, to retrieve any relevant information.

Advice and Assistance
It would be advisable to narrow the request to state only the correspondence held by the MHRA's Defective Medicines Report Centre (DMRC), about a particular product of interest (stating the PL number if it is a licenced product).

We anticipate that this information would be able to be retrieved within the appropriate cost limits. Once this request has been fulfilled, you would be able to request the information for other specific products.

Please note that, whilst batch release sites for licenced products are publicly available (this information is stated in the Patient Information Leaflet, which can be found at MHRA Products | Home), we do not routinely release information that could link particular manufacturing sites to the manufacture of specific products, as this information is considered to be commercially sensitive.

Please also note that the MHRA-GMDP database holds information issued by the MHRA relating to manufacturing and wholesale authorisations and certificates. Some of the information that you have requested may be publicly available here: https://cms.mhra.gov.uk/mhra

If you do submit a refined request, this will be a new request and the 20 working day statutory time limit will begin from the date your refined request is received.

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.

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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or by writing to:

Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre

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

Yours sincerely,

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