FOI 23-192 – Lithium

MHRA RESPONSE PART 1
13 April 2023

Dear

I refer to your information request, dated 16 March 2023, in which you asked for:

"1. The original clinical evidence/clinical trials leading to approval of and demonstrating the efficacy of Lithium in the treatment of bipolar disorder 2. The evidence detailing potential side effects of Lithium
3. The most recent review evidence confirming the safety and efficacy of Lithium 4. Any medicines, drugs, interventions and/or procedures refused for the treatment of bipolar disorder 5. Relating to the above point, reasons for refusal to grant any licences"

I am writing to advise you that, unfortunately, we will not be able to respond to your FOI request within the working 20 days set out in the Freedom of Information (FOI) Act.

Based on the nature of your case, some of the information you have requested falls under Section 43 (Commercial interests) of the Freedom of Information Act. Section 43 is a qualified exemption which means that we need to consider whether the public interest in releasing the information is outweighed by the public interest in not giving the information (the "public interest test").

The Marketing Authorisation Holder for lithium requires additional time to consider the application of Section 43 to the documentation we propose for release. The FOI Act allows us to extend the deadline for reply beyond the usual 20 working days in order to consider the public interest test. As a result, the new deadline for responding to your request will now be Tuesday, 16 May 2023.

At this juncture we can provide responses to questions 3 and 5 of your request, see below.

Q.3 The most recent review evidence confirming the safety and efficacy of Lithium
Our response: We are not aware of any recent safety reviews, however, the next Periodic Safety Update Report is due to be submitted to regulators across the EU in Nov 2023.

Q.5. Relating to the above point, reasons for refusal to grant any licences
Our response: There have been no refusals of Marketing Authorisations in the UK for lithium for in use of bipolar disorder.

Once the public interest test has concluded, we will issue you with our full reply.

Kind regards,
HQA FOI Team

MHRA RESPONSE PART 2
23 May 2023

Following on from our message below, we are now in a position to respond to your remaining questions—our apologies for the delay.

To firstly address questions 1 and 2,

"1. The original clinical evidence/clinical trials leading to approval of and demonstrating the efficacy of Lithium in the treatment of bipolar disorder 2. The evidence detailing potential side effects of Lithium."

We have interpreted this request to relate to the original approval, however, please note that side effects based on recent data are listed in the patient information leaflet and section 4.8 of the summary of product characteristics (SmPC). These documents can be located by searching here: MHRA Products | Home

Lithium products for use in mania and hypomania, or bipolar as the condition is now known, were originally afforded product licences of right (PLRs), once data were accrued and if a company wished to continue to market their product in the UK, a PLR had to undergo a review by the MHRA and the findings and evidence were then considered by the Commission on the Review of Medicines (CRM). We attach the CRM considerations with regard to the lithium products granted the first product licences in the UK (current terminology, marketing authorisations). We also attach the product particulars associated with the initial licence for 'Priadel' which was the first lithium product granted a medicines licence in the UK., pages 5 – 7 details side effects and precautions.

Priadel was first licensed in September 1968, followed by Phasal in November 1973, Camcolit 250 mg (Norgine) in January 1976 and. Camcolit 400 mg (originally but mistakenly thought to be a slow release preparation) in April 1977 (ref: page 40 of the attached 'lithium pages redacted file').

In answer to the only remaining question (Q.5), which related to **any refusals to grant marketing authorisations/product licences**, according to our regards none have been refused. However, historically, there have been a small number of applications where the applicant has decided to withdraw their application.
We trust that you will find the above and attached of use.

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 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
Medicines and Healthcare products Regulatory Agency
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Yours sincerely,
HQA FOI Team