Medicines & Healthcare products Regulatory Agency

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

[redacted]

16 October 2023

Dear [redacted]

RE: FOI 23-521 Non-compliance with sertraline licence

Thank you for your request of 13 July 2023 under the Freedom of Information Act for the following:

1. The exact date of this license change (approximately August 2018)
2. Date of request from MHRA (and/or European equivalent if relevant) to all 28 UK sertraline MAH to update their sertraline PIL in accordance with the license.
3. The timeframe required by MHRA for submission of the updated PIL.
4. The date that MHRA received the updated PIL for each sertraline product from each MA holder.
5. A copy of each updated PIL for each product for each MAH (I will look through them all).
6. The date Marketing Authorisation renewal was issued to each MAH
7. The report provided by each MAH detailing user consultation with target patient groups on the PIL.
8. Details of any testing of communication of suicidal ideation in any context by sertraline MAH.

The exact date of this license change (approximately August 2018)

The variation to update the product information for Lustral (PL 0057/0308 and PL 0057/0309) was approved by the MHRA on 21/8/2018 following approval of the changes by the Reference Member State the Netherlands within a European procedure.

Date of request from MHRA (and/or European equivalent if relevant) to all 28 UK sertraline MAH to update their sertraline PIL in accordance with the license.

Marketing Authorisation Holders (MAHs) must keep their product information up-to-date in the light of scientific knowledge. The MAHs pharmacovigilance system must include specific quality systems to ensure this occurs.

Neither the MHRA nor the equivalent European regulatory authority specifically requested the MAHs for products containing sertraline to update their materials in line with the updates made to Lustral.

The timeframe required by MHRA for submission of the updated PIL.
The medicines regulations do not impose a specific timeframe that MAHs are required to submit variations to their product information.

The date that MHRA received the updated PIL for each sertraline product from each MA holder.

Although this data is held by the MHRA, it cannot be easily extracted and would require manual review of the variation procedures for each product licence. Given it required over 1 hour to search and confirm the variation to update Lustral was received on 3/8/2017 prior to its approval on the MHRA's system on 21/8/2018, review of each product licence for sertraline containing products would exceed 24 hours. Therefore, we have determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process this aspect of your request.

Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

A copy of each updated PIL for each product for each MAH (I will look through them all).

Section 21 of the Acts allows public authorities to refuse requests where the information is accessible by other means. The currently granted Patient Information Leaflets (PIL) for sertraline products can be found on the MHRA website at the following link: MHRA Products | Substance. Therefore copies of each PIL have not been provided.

Attached at Annex 1 is a table of sertraline products that were authorised in 2018 which should help you, should you wish to review each PIL.

The date Marketing Authorisation renewal was issued to each MAH

Every product licence or marketing authorisation held by MAHs must be maintained to reflect current knowledge and is subject to renewal. The Human Medicines Regulations define the renewal requirements. Generally, each marketing authorisation is renewed after 5 years but can be subject to further renewals if conditions are applied. The dates of renewal of the authorisation are included in the table attached at Annex 1. Please note that some products have renewals pending but this does not impact on their ability to be marketed.

The report provided by each MAH detailing user consultation with target patient groups on the PIL.

All Marketing Authorisation Holders must provide evidence that the provisions of the Human Medicines Regulations in relation to the format and content of the Patient Information Leaflet have been met. However, this does not mean that formal user testing will have been carried out on all PILs. The updates made to Lustral, approved on 21/8/2018 did not include formal user testing of the product information in the dossier submitted to the MHRA.

Details of user testing cannot be easily identified within our database and would require manual review of each product licence. Therefore, we have determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process this aspect of your request.

Details of any testing of communication of suicidal ideation in any context by sertraline MAH.

Following UK and European safety reviews, the wording below on the risk of suicidal thoughts and behaviour with antidepressants was agreed in Europe in 2008 for inclusion in PILs for all antidepressants, including SSRIs and SNRIs.

'*Thoughts of suicide and worsening of your depression*

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

• if you have previously had thoughts about killing or harming yourself.

• if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

→ If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

***You may find it helpful to tell a relative or close friend** that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.'*

The sertraline MAHs did not carry out any testing of this wording.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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,
Safety & Surveillance