Safeguarding public health

MHRA

[redacted]

19 December 2007

Dea[redacted]

FOI 07 355 - Strattera

I am writing to you about a Freedom of Information Act (FOIA) request that we have received in relation to fatal reports in under 18s for Strattera. The request we have received is at Annex A.

We have already informed the requestor that, to date, the MHRA has not received any fatal suspected ADR reports associated with atomoxetine, in children below 18 years of age. (Annex B) The requestor has now asked for global data, as they have become aware of some possible fatal reports from the FDA.

The MHRA does not hold a figure for global, cumulative, fatal suspected ADRs for Strattera but to answer this request we would need to calculate this from the PSURs we have received. This may result in some double counting, due to reports appearing twice if followed up in subsequent PSURs.

We therefore feel that the best way to answer this request would be if you provide us with the most accurate and up-to-date figure data so that we can provide it to the requestor. I am unable to tell you who the requestor is, but the reply will include the following copyright notice:

> *The information supplied in response to your request is the copyright of MHRA and/or a third party or parties, and has been supplied for your personal use only. You may not sell, resell or otherwise use any information provided without prior agreement from the copyright holder. For full details on our copyright policy please visit:*

Medicines and Healthcare products Regulatory Agency
Market Towers 1 Nine Elms Lane London SW8 5NQ
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

http://www.mhra.gov.uk/home/Idcplg?IdcService=SS_GET_PAGE&nodeId=412

or e-mail the MHRA Information Centre at info@mhra.gsi.gov.uk

Our final deadline for response under the FOIA is Thursday 3 January 2008. I realise that this is a busy time of the year but if you could provide a figure by then I would be grateful. I am out of the office 22-30 December inclusive but in the office on 31 December and 1-3 January 2008.

If you are unable or unwilling to provide this data please let me know as soon as possible so that I can try to extract the figure from the PSURs we have received.

Yours sincerely

[redacted]

Information for Public Health Group, VRMM
Medicines and Healthcare products Regulatory Agency (MHRA)
Market Towers 14-110
1, Nine Elms Lane
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SW8 5NQ
Tel: 020 7084 2788
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Annex A request

Dear [redacted]

The answer I received must be based on a misunderstanding.

I am not asking **IF** there are any "fatal suspected ADR reports". Instead I attached the reports that have been sent to the FDA 2006-2007. Data from FDA say that **52 persons died in connection with Strattera treatment 2004-2006. AND: 29 of these persons were children and adolescents below the age of 18.**

My question to the MHRA was not aimed only for UK, as the agency has the overall responsibility for and is coordinating the safety work for Strattera internationally (in Europe). It is understood that the agency as part of the work with PSURs is gathering international data about fatal ADRs.

So I ask again: ***How many children below the age of 18 (in addition to the 29 mentioned in the attached file) have died in connection with Strattera treatment since the drug was approved in 2002?***

Annex B - Reply already sent

FOI 07 323 Adverse Drug Reaction (ADR) reports associated with atomoxetine (Strattera)

Dear XXX

Thank you for your enquiry of 4th November 2007 requesting information on the number of fatal suspected ADR reports associated with atomoxetine (Strattera), reported in children.

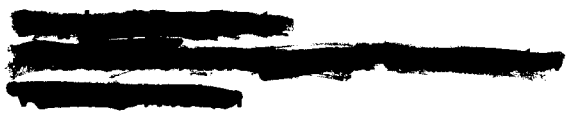
The Medicines and Healthcare products Regulatory Agency (MHRA) receives reports of suspected adverse reactions (ADRs) to medicines and vaccines from healthcare professionals and patients via the Yellow Card Scheme. Pharmaceutical companies are also under a legal obligation to report serious suspected ADRs associated with their products to the MHRA. Information collected through the scheme is an important means of monitoring drug safety in normal clinical practice, by increasing knowledge about known ADRs and acting as an early warning system for the identification of previously unrecognised ADRs.

To date, the MHRA are not aware of any fatal suspected ADR reports associated with atomoxetine, in children below 18 years of age.

If you require full and up to date data on fatal suspected ADR reports associated with atomoxetine in children, we recommend that you contact the marketing authorisation holder (MAH) for atomoxetine. In the UK, this is Eli Lilly & Co.

I hope this information is useful to you.

Yours sincerely,



Lilly

[redacted]

[redacted]

[redacted]

2nd January 2008

[redacted]

Information for Public Health Group, VRMM
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

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Dear [redacted]

Re: FOI 07 355 - Strattera (Atomoxetine)

Thank you for your letter of 19th December 2007, received shortly before the Christmas holiday, and seeking our response by Thursday 3rd January 2008. The question posed by the FOI requestor was "How many children below the age of 18 (in addition to the 29 mentioned in the attached file) have died in connection with Strattera treatment since the drug was approved in 2002?"

I understand from your letter that "the MHRA does not hold a figure for global, cumulative, fatal suspected ADRs for Strattera but to answer this request [the MHRA] would need to calculate this from the PSURs we have received. This may result in some double counting, due to reports appearing twice if followed up in subsequent PSURs".

Whilst we appreciate the opportunity to provide you with a figure and to assist you, we do have concerns:

1. Given the degree of work required by the MHRA in answering this request, has the MHRA not considered the effort required to do so? FOIA (at s.12(1)) provides that "a public authority [is not obliged] to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit". In this case, the limit, according to SI 2004/3244 is £450 (estimated at a rate of £25 per person per hour worked).

2. If we were to provide you with a figure, we would be going beyond that which was envisaged by FOIA (which relates to information held by public bodies, not to that supplied to them in response to a request under FOIA). However, notwithstanding our point made in paragraph 1 above, we have reviewed our data and for clarity and transparency we would like to provide the following information:

[redacted]

Using a cut-off date of 30th November 2007, Lilly has identified 39 fatal cases in our safety database regardless of relatedness in patients less than 18 taking atomoxetine. Of the 39, only 22 were Adverse Drug Reactions (ADR) with fatal outcomes. An ADR is defined as a case reported by a health care professional (HCP) or regulatory authority with a relatedness to treatment of Yes or Unknown. ADRs do not include cases where the reporter stated that the event was not related to drug therapy or cases reported by a consumer and not confirmed by an HCP.

We would like to point out the importance, please, of defining an ADR with any information that you provide to the FOI requestor.

Lilly cannot make any judgement on the accuracy of the figures provided by the FOI requestor but we would be interested in knowing the list and/or details of the 2004-2006 cases this person claims to have found from FDA data.

Finally, we should be grateful if you would please let me know what you decide to provide to the FOI requestor and any further actions as Lilly needs to be prepared for follow-up requests from the media.

Yours sincerely,

[redacted]

Direct line: [redacted]
E mail: [redacted]

Lilly

[redacted]

2nd January 2008

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1 Nine Elms Lane
London
SW8 5NQ

COMMERCIALLY CONFIDENTIAL

Dear [redacted]

Re: FOI 07 355 - Strattera (Atomoxetine)

Thank you for your e-mail confirming receipt of my fax yesterday. Unfortunately an error was identified in the information I sent you (including two cases of in utero exposures have now been identified) and therefore the revised information is as follows:

- Using a cut-off date of 30th November 2007, Lilly has identified 41 fatal cases in our safety database regardless of relatedness in patients less than 18 taking atomoxetine. Of the 41, only 24 were Adverse Drug Reactions (ADR) with fatal outcomes. An ADR is defined as a case reported by a health care professional (HCP) or regulatory authority with a relatedness to treatment of Yes or Unknown. ADRs do not include cases where the reporter stated that the event was not related to drug therapy or cases reported by a consumer and not confirmed by an HCP.

Please accept our apologies for this error.

Yours sincerely,

[redacted]

[redacted]
Direct line: [redacted]
E mail: [redacted]

[redacted]