Request-100758-e4d04b77@whatdotheyknow.com

Date 12 th March 2012

REVIEW OF FREEDOM OF INFORMATION ACT (FOIA) REQUEST FOI 12-024

1. INTRODUCTION

1.1 In an email dated 16 February 2012, Ms xxxxxxxx xxxxxxxx requested a review of the Medicines and Healthcare Regulatory Agency's (MHRA) response to her request for information about Clozapine and Amisulpride. The original FOI request was in an email dated 18 January 2012.

2. PURPOSE OF INTERNAL REVIEW

2.1 The purpose of this internal review is to determine whether the MHRA dealt properly with the applicant's requests under the Freedom of Information Act (FOIA) in its response.

The terms of reference of this review are:

- To read all correspondence between the applicant and the Agency, and any other relevant correspondence;
- To form an opinion on the handling of the correspondence by the Agency;
- To advise whether the actions taken by the Agency in reaching their decisions is justified under the FOIA;
- To make recommendations for further action by the Agency if appropriate; and
- To prepare a report of the review for the Agency and Ms xxxxxxxx.

3. Background

3.1 In her initial email of 18 January 2012, Ms xxxxxxxx asked for the following information:

How many people died in 2011 as a result of taking Clozapine?

How many people died in 2011 as a result of taking Amisulpride?

How many people died in 2011 where Clozapine was a contributory factor?

How many people died in 2011 where Amisulpride was a contributory factor?

How many people developed a heart condition on account of taking Clozapine in 2011?

How many people developed a heart condition on account of taking Amisulpride in 2011?

How many people were taking Clozapine in 2011 who were removed from the Clozaril national programme on account of significant side-effects? How many of these had a heart condition?

3.2 The MHRA responded on 15th February explaining the role of the MHRA, the nature of the yellow card adverse reaction (ADR) reporting system and the type of information that can be obtained from that system. They explained that the system relied upon voluntary reporting (although manufacturers had a legal obligation to report serious ADRs to their products. The response described the purpose of the Clozaril Patient Monitoring Scheme and summarised the numbers of reports of adverse reactions received through the yellow card scheme from both the drugs. They also enclosed detailed drug analysis prints (DAPs) for Amisulpride and Clozapine with guidance on how to interpret the data.

3.3 Ms xxxxxxxx's e-mail of 27th January asks for this response to be reviewed on the following basis:

I am writing to request an internal review of Medicines and Healthcare products Regulatory Agency's handling of my FOI request 'Clozapine and Amisulpride'.

I am very concerned about Clozapine and wish to be given the details of ALL deaths where the Coroners have given DECISIONS about deaths where patients were given Clozapine and where it was deemed to be a possible factor in death.

Where are the Coroners' Decisions?

And although you mention that there are supposed to be PILs given to patients on Clozapine there are also details NOT given to the patients.

Therefore please may I have ALL DETAILS GIVEN TO PATIENTS AND THE DATA NOT GIVEN TO PATIENTS?

It cannot be right to withhold essential data such as trials and the known toxicity of Clozapine as found around the world.

Are there any countries which BAN Clozapine?

Has Clozapine ever been banned by any country and if so, when? and has any country ever un-banned the use of Clozapine, and if so, when?

Who is liable in law if the drug is licensed for use, and the doctor prescribes it and then the patient dies?

All of these questions are vital for a national moratorium on the use of Antipsychotics and Clozapine.

3.4 The questions raised in Ms xxxxxxxx's request for a review of the initial FOI request are all new questions and unrelated to the initial questions asked.

4. CONSIDERATION OF THE ISSUES

4.1 I have considered the detail of the correspondence between MHRA and Msxxxxxxxx specifically with regard to the purpose of the FOIA and the questions she claims have not been answered from her original request FOI 12-024

4.2 Ms xxxxxxxx was given a considerable amount of detailed information regarding Clozapine and Amisulpride in response to her initial question. It is clear from the response the MHRA gave in this instance, that they do not hold exactly the answers to the specific questions raised but they gave Ms xxxxxxxx all the details they held in relation to the questions asked and they qualified the response by explaining what information they held and how it should be interpreted.

5. SUMMARY

5.1 In conclusion, l believe that the Agency has given Ms xxxxxxxx as detailed as possible answers to the questions she raised in her original request 12-024. The reasons Ms xxxxxxxx gives for her request for an internal review of the original question raises completely new questions which she should submit as a new FOIA request – although I note that some of the questions relate to information that the MHRA does not hold.

5.2 If Ms xxxxxxxx remains dissatisfied, she may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in this matter. The ICO address is listed below:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Sue Jones
MHRA Corporate Policy
12th March 2012