Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

James Kelly
Sent via email to request-479585-b581f048@whatdotheyknow.com

MHRA

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31st May 2018

Dear Mr Kelly,

FOI 18/197

Thank you for your information request, dated [23 April 2018], where you asked for;

1) *Copies of all the correspondence and dates of any telephone calls between ICO, PHSO, and MHRA between 3rd July and 11th December 2017 regarding my complaint?*

The MHRA has received one letter from the ICO, which was sent to us on 28 November 2017as attached.

We are unable to find any correspondence between the MHRA and the PHSO between 3rd July 2017 to 11th December 2017.

2) *Copies of all the information MHRA and CSM sent out to GP's and other health professionals regarding any prescribing recommendations during 2005?*

The information you have requested is already in the public domain and can be found at the websites highlighted below. The FOI Act section 21 exemption states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route.

The MHRA and CSM recommended that patients should discuss their treatment with their healthcare professional as published at the website given below. All information that was sent to GPs and other health professionals is published on the internet.

Some more specific articles are highlighted at the following website addresses.

http://webarchive.nationalarchives.gov.uk/20141206152209/http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON002065

http://webarchive.nationalarchives.gov.uk/20141206152207/http://www.mhra.gov.uk/NewsCentre/CON2025739

https://www.gov.uk/drug-safety-update/co-proxamol-withdrawal-reminder-to-prescribers

These websites contain links to all articles concerning the assessment and subsequent advice arising from investigations into the benefits and risks of co-proxamol.

3) *Please can you explain why CSM felt it necessary to inform the FDA on their ill-informed findings six months before it was debated in parliament?*

The MHRA has regular discussions with the FDA and other National Competent Authorities throughout Europe concerning safety concerns that have been investigated or are under investigation. This action is taken to ensure that all available information can be considered to protect public health both in the UK and for patients travelling to other countries. Therefore, the FDA and other National Competent Authorities were informed of the CSM recommendation in 2005.

4) *CSM had given five options for MHRA to consider, why did MHRA not disclose the other four options to Government during 2005?*

The MHRA undertook a review of all safety information obtained from all sources, including literature, clinical studies, spontaneous safety reports, and from public consultations at the time of assessment. The MHRA took advice from independent experts within the Committee on the Safety of Medicines (CSM) to come to a decision concerning the safety of co-proxamol before taking action. The decision to revoke licences for co-proxamol was based on the conclusion that the risks outweighed the benefits to patients. CSM considered all options before coming to their considered decision, this included a consideration of the effectiveness any risk minimisation measures that have been taken or those proposed. It was standard practice for the assessment reports prepared by the MHRA for CSM to include multiple options regarding possible regulatory action. The CSM recommendation was subsequently presented to Government.

5) *Did MHRA inform Ministers in 2005 that CSM's call for evidence had an extremely low response?*

All copies of public consultations and comments received are published on the www.gov.uk website. This is available to the general public including all Members of Parliament. Copies of historical documentation identified in our electronic archive pertaining to this review are attached to this letter (CSM 2004/16th)

6a) *Please could you supply any evidence that hundreds of thousands of patients wouldn't suffer any ill effects from the start of the ban (1st January 2008)?*

Please see response to questions 2 and 4.

6b) *Please could you supply copies of all documents pertaining to CSM's 'Rigorous Review' which would be of benefit to patients or reduce costs to the NHS?*

6c) *Please could you supply copies of all the correspondence with Government Ministers relating to the poor response to CSM's 'public call for evidence on the risks and benefits of co-proxamol'.*

7a) *Please can you explain why MHRA chose the BAN option when suicide rates had been decreasing between 1999 and 2004? [Attachment 4 (to FOI request)]*

7b) *Please could supply all documents relating to MHRA's decision to dismiss the other four options suggested by CSM?*

In response to the above four questions; copies of historical documentation identified in our electronic archive pertaining to this review are attached to this letter. Confidential information is redacted from the documents under FOI Act section 41 – Personal Information - – information is exempt if it contains personal data which would identify a living person. Confidential information is also redacted from the documents under FOI Act section 43 – commercial interests - this exempts information where disclosure would be likely to prejudice the commercial interests of any person. It also includes a specific exemption for trade secrets.

8a) *Please could you supply copies of all correspondence between MHRA and Government Ministers regarding MHRA's decision not to recommend controlled status for Co-proxamol?*

Decisions to classify individual drugs as controlled drugs under the Misuse of Drugs Act 1971, is undertaken by the Advisory Council on the Misuse of Drugs and is not confined to authorised medicines. Further information relating to the classification of dextropropoxyphene is available in the www.gov.uk webpages

8b) *Please could you inform me which Ministers responded, and supply all correspondence between Ministers and MHRA regarding a reconsideration of your decision to ban?*

We are unable to identify any correspondence between ministers and the MHRA on this subject from our electronic archives. The market authorisation Holders were able to appeal to the decision, and CSM took on board their responses to CSM's concerns. Therefore, the decision was reconsidered, however the concerns of CSM were not addressed and therefore the decision to withdraw Co-proxamol licences was retained. The historical documentation concerning all decisions are attached.

9) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4332124/
Re: -
"There is no robust evidence that efficacy of this combination product is superior to full strength paracetamol alone in either acute or chronic use.

Hanks Forbes report published during 1998 challenged this, stating it was very effective in 'Palliative Care'.

Please could you supply all the information MHRA used which led you to dismiss this extremely relevant report?

10) *Please could you supply all the information MHRA considered before rejecting the views of the majority of GP's and Rheumatologists in the 'Pulse Report', and your reasons why?*

Please see response to question 6b, 6c, 7a, 7b.

11) *[Page 2 Paragraph 3 Above] States CSM offered five options, and it was MHRA who advised that co-proxamol should be withdrawn from the market. Please could you clarify?*

Please see response to question 4 above.

12) *Please could you supply any evidence that shows suicides weren't reducing 1999 to 2004?*

Please see response to question 2 above

13) *Please supply copies of all the documents MHRA reviewed when they concluded that "current evidence is that previous advice in 1985 to strengthen warnings about co- proxamol overdose has not impacted on the problem." [Attachment 4 (to FOI request)] clearly shows a 7% reduction in Co-proxamol suicides prior to the ban being announced!*

Please see response to question 6b, 6c, 7a, 7b

14) *MHRA Total Gains up to 2015 Additional MA's issued for Oxycodone, Fentanyl, and Buprenorphine [Attachment 5 (to FOI request)]. It appears that MHRA are EIGHT MILLION POUNDS BETTER OFF following the additional 298 MA's you have issued since 2005 for Oxycodone, Fentanyl, and Buprenorphine!*

Please could you supply any evidence that would contradict my guestimate?

Your final question is in relation to fees associated with the application for, and upkeep of a market authorisation of a medicine. In order for a pharmaceutical company to obtain a licence for any medicine, they would need to submit an application which meets all of the current regulatory requirements set in legislation within the Medicines Act 1968, and Directive 2001/83/EC as amended. The application should show that the benefits exceed the risks, and that any identified risks or subsequently identified risks associated with the known safety concerns for the medicine, could be minimised through appropriate restrictions and monitoring.

The marketing authorisation holders (MAHs) are legally required to monitor the safety of their authorised medicines. If any new information comes to the attention of the MAHs, identified through

routine or additional pharmacovigilance, then this should be highlighted by the MAH and submitted to the regulatory authority for further assessment to ensure that patients are informed of all safety concerns associated with that medicine.

I can confirm that the costs associated with the regulation of medicines in the UK are met through fees from the pharmaceutical industry. However, the MHRA does not have any regulation over the price/cost of supplying medicines within the NHS. The MHRA is not involved with negotiating the drug tariff or establishing which medicines are included on the drug tariff list.

Regulatory fees are payable to the national competent authority who will lead on the assessment of the benefits and risks of the medicine. The MHRA does not lead the assessment for each and every individual licence, although will provide information and comments on the assessment which are pertinent to the application and the active pharmaceutical agent of the medicine. The appropriate regulatory fee will be payable to the lead member state to cover costs. Therefore, the MHRA does not receive monies to review all applications submitted. Never-the-less, the agency will assess the balance of benefits and risks of all medicines regardless of cost to the Agency. The over-riding aim of MHRA pharmacovigilance is to protect public health. The MHRA is a trading fund and the fees offset the work undertaken. The MHRA does not profit from the regulation of medicines.

All medicines have risks and can have adverse effects, although not everyone will experience them. The MHRA continually review the risks and benefits associated with the use of medicines to ensure that the benefits outweigh the risks.

The Freedom of Information Act only entitles you access to information – the information supplied is subject to Crown copyright, and there are some restrictions on its re-use. For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division