Safeguarding public health

MHRA

[redacted]

29 May 2009

FOI 09 147

Dear [redacted]

Thank you for your Freedom of Information Act (FOIA) request to the MHRA Chairman of 25 April 2009 about co-proxamol. This has been passed to me as FOIA coordinator for Vigilance and Risk Management of Medicines Division.

You have asked for a copy of each letter, fax or email that the MHRA has received about the withdrawal of co-proxamol from 1 January 2006 to 31 December 2008. Correspondence received from 1 January 2006 to 31 July 2008 has already been released under FOI references 07 347, 08 017 and 08 242 and I am enclosing copies of these for you. This information also includes some of the replies sent over that period.

I am also releasing letters received and replies sent from 1 August to 31 December 2008 with this reply. Names of MHRA staff have been removed under S38 (health and safety) of the FOIA and other personal information under S40 (personal information).

The information that you cited in paragraph 2 of your letter is correct and this statement appears on the MHRA website at the following link: http://www.mhra.gov.uk/NewsCentre/CON2025739**.**

The MHRA has also issued a reminder to prescribers about the position with co-proxamol in its drug safety bulletin, Drug Safety Update. This information can be accessed via the link cited above and at the link below:

http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON2032916.

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

With regards to your point about medical defence organisations, as the MHRA is independent of Government we cannot comment on the cover provided by them for GPs who prescribe co-proxamol or any other unlicensed medicine. Individual GPs who have a concern over their indemnity cover should discuss this directly with the relevant organisation. The MHRA has sought legal advice on the possibility of a legal disclaimer to support doctors in prescribing unlicensed co-proxamol. The legal advice was that if unlicensed co-proxamol is prescribed, the doctor must take direct personal responsibility for this. A patient disclaimer/consent form cannot remove or satisfy that requirement as a doctor still has a responsibility to exercise his or her clinical judgment as well as a separate legal obligation to obtain informed consent to any treatment.

The supply of unlicensed medicines is not an unusual arrangement and medicines may be supplied on this basis, but the responsibility for deciding whether or not to make use of that provision lies with the prescriber. The risks and benefits of the continued supply of an unlicensed medicine for individual patients must be weighed up by the prescriber in consultation with the patient.

The MHRA has issued advice for health professionals on off-label and unlicensed use of medicines and this is published in the April 2009 edition of Drug Safety Update, which can be accessed via the link below. This advice is based on guidance on good practice issued by professional bodies such as the General Medical Council (GMC).

http://www.mhra.gov.uk/Publicat[redacted]ce/DrugSafetyUpdate/CON043809

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The decision to withdraw co-proxamol from the market has tested medicines regulation to the extreme. Weighed against the difficulty for individual users is the clear public health gain from the removal of a medicine which has been widely implicated in accidental and non accidental overdose. Sometimes regulation has to balance the needs of the individual against the benefits at a population level. In this case the removal of marketing authorisations with continued use possible in exceptional circumstances is the best balance that could be achieved.

It is encouraging to see that the public health gain from the withdrawal of co-proxamol is already becoming apparent. The withdrawal in the UK has saved approximately 300 lives per year and there is no evidence that the death rate due to other analgesics is increasing.

If you have a query about this letter, please contact me. If you are unhappy with our decision to withhold certain information, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 10th Floor, Medicines and Healthcare products Regulatory Agency, at the above address quoting the above reference. After that, if you remain dissatisfied, you may ask the Information Commissioner at

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

to make a decision on whether or not we have interpreted the FOIA correctly in withholding information from you.

Yours sincerely

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Freedom of Information Coordinator
Vigilance and Risk Management of Medicines Division