

## **Internal Review FOI 20/159**

### **1. Introduction**

Dear James Kelly,

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your Freedom of Information (FOI) request 20/159.

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA).

Your original request and the Agency's response are annexed.

You stated in your request for this review that pricing of co-proxamol is so erratic that NHS Business Services Authority would not be in a position to help, and that the only reason for this erratic pricing is the recommendations stipulated by MHRA that each CCG has to order co-proxamol individually, resulting with the cost to the NHS reaching an alarming level, and you requested some information under FOI, noted below.

### **2. Consideration of the issues**

Has the Agency answered the request and have any exemptions been properly applied?

Having read through the available documentation in the form of an e-mail chain, there appear to be a number of areas which required attention, not all of which are appropriate to a Freedom of Information request;

- (i) There is a statement that there needs to be an urgent review of the co-proxamol decision. This is being dealt with separately as a query by the Customer Services team reference 3960.
- (ii) There is a request for pricing information, specifically asking that importers which supplied certain trusts/entities be named.
- (iii) There is a request for information relating to the number of Marketing Authorisations issued for a subset of products, Oxycodone, Fentanyl, Buprenorphine and Tramadol for the period 2005 to 2019.

Has the Agency fulfilled its general obligation to be helpful?

The Agency has in general been helpful in trying to fulfil the FOI portion of the request, providing the requested information which falls within the remit of the Agency i.e. information relating to the number of Marketing Authorisations issued for a subset of products, Oxycodone, Fentanyl, Buprenorphine and Tramadol for the period 2005 to 2019.

However, even though pricing falls outside of the remit of the Agency, we could have been more helpful in trying to help you source the pricing information. In that spirit, I approached DHSC for the requested information on importers who had supplied the named entities, their response was as follows: “We have reviewed the Freedom of Information request submitted to the MHRA regarding the pricing of Co-Proxamol. Unfortunately, the Department does not hold the information relevant to the request”.

### **3. Conclusion and recommendations**

Having reviewed the original request and subsequent Agency response, the Agency has met all the requirements of the FOIA by providing all the information held within the required timelines.

The Agency could have been more helpful in providing you with advice for sourcing the pricing information, however this falls outside of the remit of the FOI process. The main subject of your email, on how co-proxamol is handled by the Agency, is being dealt with by the Customer Services team outside of FOI under reference 3960.

If you remain dissatisfied, you may ask the Information Commissioner (ICO) to decide on whether we have interpreted the FOIA correctly in dealing with the request and subsequent internal review.

The ICO’s address is:

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

**Sean Kaiser**

## **Annex: background correspondence**

### **Initial FOI request received from James Kelly**

Dear All,

This is a Freedom of Information request FOI 20/159.

Dear Francisco, in terms of the 1st question it focuses around importing unlicensed medicines and costs so for this would enquirer be referred to DHSC for a response?

Dear Mark, for question 2 the enquirer is asking for MAs issued between 2005 and 2019. Can this be logged ISE?

As it's sensitive the deadline for reply is 27/04/2020 for NDC team to review the draft response. The 20 day deadline for reply is 04/05/2020.

We believe this might be a sensitive case. The FOI Policy team and News Centre need to see draft responses to sensitive cases with 5 days' notice – please can you move these ones to the front of the queue. This is to provide enough time to review and comment and arrange high level clearance, if needed. Sensitive cases are flagged in the twice-weekly reminder emails. The Customer Services team will also send these out. Each division is responsible for ensuring a full and final draft is sent to customer service.

- If the case concerns a wider ongoing topic, please ensure consistency with other communications (eg providing additional context in the reply).
- Click here for FOI guidance and here for reply templates.
- Divisional FOI leads, click here for the shared FOI case tracker.

The FOI Policy team are happy to help if you have any questions.

Many thanks

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000

### **FOI request background information supplied by James Kelly**

-----Original Message-----

From: James Kelly <[request-657592-f72a6a1c@whatdotheyknow.com](mailto:request-657592-f72a6a1c@whatdotheyknow.com)>

Sent: 02 April 2020 01:45

To: MHRA Customer Services <[MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)>

Subject: Freedom of Information request - Co-proxamol Inconsistent Pricing

Dear Medicines and Healthcare products Regulatory Agency, Background to my request.

Co-proxamol is continuing to be prescribed today and due to the ridiculous guidelines MHRA stipulate for the importation of unlicensed / off label medications some CCG's have to pay £5.22 per tablet when they could be imported for approximately £0.05 per tablet if the NHS purchased in bulk!

If the NHS could have purchased in bulk quantities the remaining 60,000 named patients would have continued to benefit from suitable analgesia which had been guaranteed by June Raine (MHRA) and Caroline Flint (Minister for Public Health during 2007)!

Extracts from Openprescribing.net March to December 2019

[https://urldefense.proofpoint.com/v2/url?u=https-3A\\_\\_openprescribing.net\\_national\\_england\\_0407010Q0AAAAAA\\_price-2Dper-2Dunit\\_-3Fdate-3D2019-2D03-2D01&d=DwIFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCCQj1uNM&r=km\\_DIOctokEVZj2AvNH6w&m=PA3u9vI0JQ5F906JRHGEa6gLRxCuU1nwEcRsuZLkBU&s=xxZR3K-gCKNxdPtAuTPJd1YbnNGh989IEwISLfo7qrk&e=](https://urldefense.proofpoint.com/v2/url?u=https-3A__openprescribing.net_national_england_0407010Q0AAAAAA_price-2Dper-2Dunit_-3Fdate-3D2019-2D03-2D01&d=DwIFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCCQj1uNM&r=km_DIOctokEVZj2AvNH6w&m=PA3u9vI0JQ5F906JRHGEa6gLRxCuU1nwEcRsuZLkBU&s=xxZR3K-gCKNxdPtAuTPJd1YbnNGh989IEwISLfo7qrk&e=)

#### NHS South Kent Coast CCG

##### Price per Tablet / Quantity Ordered

March	2019	£0.46
600		
April	2019	£3.26
200		
May	2019	£0.74
400		
June	2019	£0.91
620		
July	2019	£1.17
1200		
August	2019	£0.84
400		
September	2019	£1.05
600		
October	2019	£1.07
700		
November	2019	£0.87
400		
December	2019	£1.05
700		

#### NHS Enfield CCG

July 2019	£5.22	100
December 2019	£5.22	
100		

(Dec 2019 Last Available Data)

FOI request:

- Please name the Importers who charged:
  - South Kent CCG just £0.46 per tablet during March 2019
  - South Kent CCG £3.26 per tablet during April 2019
  - NHS Enfield CCG £5.22 per tablet during July and December 2019
- Total numbers of Marketing Authorisations issued up to 2005 and the numbers issued between 2005 and 2019 for:
  - Oxycodone
  - Fentanyl
  - Buprenorphine
  - Tramadol

Yours faithfully,

James Kelly

### **MHRA response to FOI request from James Kelly**

FOI 20/159

Dear Mr Kelly,

Thank you for your email of 2 April where you have asked " FOI request:

1. Please name the Importers who charged:

- a) South Kent CCG just £0.46 per tablet during March 2019
- b) South Kent CCG £3.26 per tablet during April 2019
- c) NHS Enfield CCG £5.22 per tablet during July and December 2019

2. Total numbers of Marketing Authorisations issued up to 2005 and the numbers issued between 2005 and 2019 for:

- a) Oxycodone
- b) Fentanyl
- c) Buprenorphine
- d) Tramadol"

A medicinal product must be the subject of a marketing authorisation or product licence before being placed on the market (regulation 46 of the Human Medicines Regulations 2012). Regulation 167 of those 2012 Regulations provides an exemption from the need for a marketing authorisation for a medicinal product. Unlicensed medicines, also referred to as specials, are products which have been specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients.

An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient. Responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet should be a matter for the prescriber responsible for the patient's care. The importation of the product as a special may take place on the understanding that it does not displace that critical role of clinicians and their responsibilities to patients.

The details of the supply of unlicensed medicinal products are explained in the MHRA Guidance Note 14 - The supply of unlicensed medicinal products ("specials"):

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/373505/The\\_supply\\_of\\_unlicensed\\_medicinal\\_products\\_specials.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf)

The importer of an unlicensed medicinal product into the UK must be suitably licensed. Information is found in the link above.

Pricing of medicinal products is outside the scope of the work of the agency and we do not hold such data. The Department of Health may hold data pertaining to the cost of products – please contact them directly at the following email address: [freedomofinformation@dh.gsi.gov.uk](mailto:freedomofinformation@dh.gsi.gov.uk)

If you have questions regarding the pricing of medicines, we advise you to contact the NHS Business Services Authority regarding pricing medication in the NHS:

Email: [PrescriptionPricingHelpdesk@ppa.nhs.uk](mailto:PrescriptionPricingHelpdesk@ppa.nhs.uk)

Please find a list below of the number of Marketing Authorisations issued up to 2005 and the numbers issued between 2005 and 2019:

a) Oxycodone Up to beginning of 200517  
2005-2019 251

b) FentanylUp to beginning of 200523  
2005-2019125

c) BuprenorphineUp to beginning of 200514  
2005-2019118

d) TramadolUp to beginning of 200575  
2005-201978

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.

The Freedom of Information Act only entitles you to 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 have a query about the information provided, please reply to this email.

Yours sincerely,

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000

### **FOI review request from James Kelly**

Dear Medicines and Healthcare products Regulatory Agency,

Please pass this on to the person who conducts Freedom of Information reviews.

I am writing to request an internal review of Medicines and Healthcare products Regulatory Agency's handling of my FOI request 'Co-proxamol Inconsistent Pricing'.

Re your response "If you have questions regarding the pricing of medicines, we advise you to contact the NHS Business Services Authority regarding pricing medication in the NHS:

As the pricing of co-proxamol is so erratic NHS Business Services Authority wouldn't be able to help! The only reason for the erratic pricing is because the recommendations stipulated by MHRA that each CCG has to order Co-proxamol individually resulting with the cost to the NHS reaching an alarming level! Please reference this request for review to the additional email "additional information to FOI 20/159

A full history of my FOI request and all correspondence is available on the Internet at this address: <https://urldefense.proofpoint.com/v2/url?u=https->

[3A www.whatdotheyknow.com request co-5Fproxamol-5Finconsistent-5Fpricing&d=DwICaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCCj1uNM&r=km\\_DIOctokEVZj2AvNHi6w&m=S\\_0OzHac1R8q5a9RkCgQ04hSWfzCC1PzyenAKIPVTv4&s=lkwCnckggFoNWFVENSWFZopiTmJkvHk-OuLx98u8ZU&e=](http://www.whatdotheyknow.com/request/co-5Fproxamol-5Finconsistent-5Fpricing&d=DwICaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCCj1uNM&r=km_DIOctokEVZj2AvNHi6w&m=S_0OzHac1R8q5a9RkCgQ04hSWfzCC1PzyenAKIPVTv4&s=lkwCnckggFoNWFVENSWFZopiTmJkvHk-OuLx98u8ZU&e=)

Yours faithfully,

James Kelly