# Freedom of Information Act 2000 (FOIA)

# Decision notice

**Date:** 15 August 2022

**Public Authority:** Medicines and Healthcare products Regulatory Agency

**Address:** 10 South Colonnade
Canary Wharf
London
E14 4PU

## Decision (including any steps ordered)

1. The complainant has requested the names of licenced importers of co-proxamol over a 10 year period. The Medicines and Healthcare products Regulatory Agency (MHRA) withheld the information under section 43(2) of FOIA, which concerns commercial interests. MHRA subsequently confirmed that it is also relying in section 41(1) of FOIA to withhold the information, as it considers it to be information provided to MHRA in confidence.

2. The Commissioner's decision is as follows:

   - The withheld information does not engage the exemptions under section 41(1) or 43(2) of FOIA.

3. The Commissioner requires MHRA to take the following step to ensure compliance with the legislation:

   - Disclose to the complainant the information it is withholding under the above two exemptions.

4. MHRA must take this step within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

## Context

5. MHRA has told the Commissioner that it has had a history of correspondence with the complainant on the subject of the importation of co-proxamol into the UK as an unlicensed medicine. An unlicensed medicine is one without a marketing authorisation issued by MHRA, and which has not been evaluated by MHRA for its quality, safety or efficacy.

6. Unlicensed medicines can be imported into the UK following prior notification to MHRA by licenced importers. In order to import the medicine, the importer will require a letter issued by MHRA not objecting to the request.

7. Co-proxamol is an analgesic medicine, used to relieve pain and inflammation, which has been unlicensed in the UK since 2007. A provision remains for the supply of unlicensed co-proxamol on the responsibility of the prescriber.

## Request and response

8. On 8 April 2021 the complainant wrote to MHRA and requested information in the following terms:

> "Please can you reveal the identity (names) of all the licenced importers of Co-proxamol from May 2008 to February 2018?"

9. MHRA responded on 6 May 2021 but reproduced the request as being the following:

> "1.My request relates to the information you provided on 4th September 2018 "Co proxamol information 2007 2018.xls file" which disclosed every application to import Co-proxamol with the importer names redacted.
>
> As you're aware the ICO Commissioner considered whether the MHRA had correctly applied section 41 and/or 43 of the FOI act to withhold the names of the licenced importers and decided you hadn't, as you hold all the requested information you should disclose this information immediately.
>
> Please can you remove all the redactions on this xls file you previously supplied?
>
> 2.Please can you reveal the identity (names) of all the licenced importers of Co-proxamol from May 2008 to February 2018?"

10. MRHA gave the request(s) the references FOI 21/376 and FOI 21/465. It advised that it had responded to the request previously and held no further information. It referred to the exemption under section 14 of FOIA which concerns repeat requests.

11. The complainant requested an internal review on 7 May 2021, as follows:

> "The information you have previously provided is not date specific. In order for me to identify the importers who are seriously overcharging the NHS I need to have date specific information. I would be grateful if you could supply the importer names for the following Month / Year dates: -
>
> May/08, May/08, Oct/08, Oct/08, Oct/08, Oct/08, Nov/08, Mar/09, Apr/09, Apr/09, May/09, Jul/09, Jul/09, Aug/09, Sep/09, Sep/09, Oct/09, Nov/09, Dec/09, Jan/10, Jan/10, Jan/10, Feb/10, Feb/10, Feb/10, Mar/10, Apr/10 Apr/10, Apr/10, Apr/10, May/10, May/10, Aug/10, Sep/10, Oct/10, Nov/10, Dec/10, Jan/11, Jan/11, Jan/11, Feb/11, Mar/11, May/11, Sep/11, Oct/11, Nov/11, Nov/11, Nov/11, Feb/12, May/12, Jun/12, Nov/12, Mar/13, Apr/13, Oct/13, May/14, Apr/15, Oct/15, Oct/15, Dec/15, Jan/16, Feb/16, Mar/16, Mar/16 Apr/16, Apr/16, May/16, Dec/17, Feb/18"

12. MHRA responded on 7 June 2021 under a new reference – FOI 21/506. It again advised that it had responded to the request previously and held no further information. MHRA again referred to the exemption under section 14 of FOIA.

13. The complainant requested an internal review on 8 June 2021, providing reasons why MHRA should disclose the importers' names.

14. MHRA provided an internal review on 13 July 2021. It said it had responded to all the complainant's questions in past communications. It noted that in a response of 16 December 2020 to a previous request, MHRA had provided the complainant with:

- the names of importers that notified their intent to import the products the complainant had enquired about over the date period
- the number of notifications of intent to import that each importer had submitted over the date period; and
- the number of notifications of intent to import the MHRA received each year over the date period.

15. MHRA went on to advise that it was not able to provide information in "the format" the complainant had requested because it is exempt under section 43 and the public interest favoured maintaining the exemption.

## Scope of the case

16. The complainant contacted the Commissioner on 15 July 2021 to complain about the way their request for information had been handled.

17. On 9 August 2022 MHRA provided the complainant with a fresh response in which it advised that it considered that the information it is withholding is also exempt under section 41(1) of FOIA. The complainant confirmed to the Commissioner on 11 August 2022 that they remained dissatisfied.

18. The Commissioner's investigation has focussed on MHRA's reliance on section 41(1) and/or section 43(2) to withhold information requested on 7 May 2021, and the balance of the public interest where relevant and if necessary.

## Reasons for decision

### Section 41 – information provided in confidence

19. Section 41(1) provides that information is exempt if, under subsection (a) the public authority obtained it from any other person and, under subsection (b), disclosure would constitute a breach of confidence actionable by that person or any other person. This exemption is absolute and therefore not subject to a public interest test, as such.

**a) Did MHRA obtain the information from another person?**

20. The requested information is the names of licenced importers of co-proxamol [who applied to MHRA to import co-proxamol-containing medicines] over specific months from May 2008 to February 2018. The Commissioner is satisfied that MHRA obtained that information from other people – the licenced importers.

**b) Would disclosure constitute a breach of confidence actionable by that person or another person?**

21. In considering whether disclosing the information constitutes an actionable breach of confidence the Commissioner considers the following:

- whether the information has the necessary quality of confidence;
- whether the information was imparted in circumstances importing an obligation of confidence; and
- whether disclosure would be an unauthorised use of the information to the detriment of the confider.

22. **Necessary quality of confidence:** The Commissioner considers that information will have the necessary quality of confidence if it is not otherwise accessible, and if it is more than trivial.

23. In its section 41(1) submission dated 26 July 2022 MHRA has noted that it has previously provided the importers' names to the complainant in the context of the total number of notifications of intent to import co-proxamol-containing medicines that it had received from each importer over a 12 year period. MHRA also discussed why the information the complainant is seeking will not be of use to them.

24. What is being requested here is the names of the licenced importers of co-proxamol against the dates on which those companies applied to MHRA for their letter of no-objection.

25. In its submission to the Commissioner MHRA has discussed what it considers to be the complainant's aim behind their request and why the information they have requested will not, ultimately, help them to achieve their aim. MHRA has not explained why, although it has already disclosed the names of the importers in one particular context, those names are nevertheless not otherwise accessible. Nonetheless Commissioner will accept that the specific information requested is not otherwise accessible.

26. However, the Commissioner does not accept that the requested information has the necessary quality of confidence. This is because the importers' names **are** already in the public domain and therefore, he considers the information requested to be trivial.

27. Based on MHRA's submission to him, the Commissioner must therefore find that the requested information lacks the necessary quality of confidence and so the condition under section 41(1)(b) is not met. As such, MHRA cannot rely on section 41(1) of FOIA to withhold the information. The Commissioner has gone on to consider MHRA's application of section 43 to the information.

**Section 43 – prejudice to commercial interests**

28. Section 43(2) of FOIA says that information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the

commercial interests of any person (including the public authority holding it). Section 43(2) is subject to the public interest test.

29. The Commissioner considers that in order for this exemption to be applicable, three criteria must be met. First, the actual harm that the public authority alleges would, or would be likely, to occur if the withheld information were disclosed must relate to the applicable interests within the relevant exemption. Second, the public authority must be able to demonstrate that some causal relationship exists between the potential disclosure of the information being withheld and the prejudice which the exemption is designed to protect. Furthermore, the resultant prejudice that is alleged must be real, actual or of substance. Third, it is necessary to establish whether the level of likelihood of prejudice being relied upon by the public authority is met – eg disclosure 'would be likely' to result in prejudice or disclosure 'would' result in prejudice

30. The Commissioner noted that he had issued a decision notice against MHRA on 23 May 2019 (FS50796228[1]) ordering it to disclose the names of licensed importers of co-proxamol from 1 November 2015 to the date of the request in that case. He advised MHRA that he was not aware that MHRA had appealed that decision and so assumed MHRA must have complied with that notice and disclosed the information ie the names of the co-proxamol importers. He queried why MHRA was again seeking to withhold similar information under section 43.

31. In its initial submission to the Commissioner of 7 June 2022, MHRA first explained that it had reviewed its correspondence with the complainant, over several years, about the importation of co-proxamol into the UK as an unlicensed medicine. MHRA explained that an unlicensed medicine is one which does not hold a Marketing Authorisation. The presence of a Marketing Authorisation denotes that MHRA has evaluated the product and is assured it meets the required standards of safety, quality and efficacy.

32. Where a medicine is unlicensed it can be imported into the UK by licenced importers. However, in order to import the medicine, the importer will notify MHRA of its intention prior to import and will not be able to proceed unless MHRA issues a letter of non-objection. If MHRA does object, then the importation cannot proceed.

[1] https://ico.org.uk/media/action-weve-taken/decision-notices/2019/2615026/fs50796228.pdf

33. When they submit their notifications, importers must provide commercial and scientific information. This information is provided in confidence as part of the regulatory process and allows MHRA to conduct a risk-based assessment of the notification and make a decision as to whether it can proceed.

34. MHRA said it considers that this information, provided for the regulatory purpose described above, is bound by the common law duty of confidentiality. This means it is not to use the information for a different purpose, or to disclose the information to others without explicit consent from the importer, unless required to do so by law or where there is an overriding public interest in disclosure.

35. MHRA said that it considers that it cannot fulfil the complainant's request without disclosing commercially sensitive information, and it does not believe the public interest is best served by releasing that information.

36. By way of background, MHRA also told the Commissioner that the complainant has submitted previous requests (FOI 18/458 and 20/549) and it has provided information to them in response to those requests.

37. In its FOI 18/458 response, MHRA supplied a spreadsheet ('Copy of Co-proxamol information 2007-2018 (002)'), in which it provided details on the supply chain and quantities of imports for each of the data periods. MHRA redacted the names of the importers [in column B] so as not to infringe on their commercially sensitive information. The remaining columns are headed: Notification Month/Year, Bulk Importer Code, Exporting Country, Manufacturer, Manufacturer Country, Non-Propriety Product, Propriety Name, Pack Size, Number of Packs per Notification and Number of Notifications.

38. In the subsequent request, FOI 20/549, MHRA disclosed the names of the importers for the date period originally requested and further broke down the total number of imports by each importer to assist the complainant. In responding to that request the information was provided in the following format:

> "The table below shows how many notifications of intent to import unlicensed CO-PROXAMOL containing products the MHRA has received each year for the date period 01-Jan-2007 to 23-Aug-2018. Please note that these are notifications of **intent to import** the medicines. This does not mean that the importers have actually imported the medicines. **The MHRA is not informed when or if the importation actually takes place.**

Also, the MHRA does not keep a register and is not informed of unlicensed CO-PROXAMOL containing products that are manufactured in the UK.

| Year of notification to the MHRA | Total number of notifications of intent to import |
|---|---|
| 2007 | 554 |
| 2008 | 2351 |
| 2009 | 10126 |
| 2010 | 14524 |
| 2011 | 3113 |
| 2012 | 4841 |
| 2013 | 6115 |
| 2014 | 2002 |
| 2015 | 2692 |
| 2016 | 811 |
| 2017 | 1 |
| 2018 | 1 |
| Total: | 47131 |

The table below shows the importers that have notified the MHRA of their intent to import these unlicensed medicines and how many notifications have been successfully processed for each one.

| Importer Name | Total number of notifications of intent to import for date period 01-Jan-2007 to 23-Aug-2018 |
|---|---|
| Redacted | 1 |
| Redacted | 2336 |
| Redacted | 5908 |
| Redacted | 1231 |
| Redacted | 35970 |
| Redacted | 1 |
| Redacted | 334 |
| Redacted | 60 |
| Redacted | 170 |
| Redacted | 1120 |

39. MHRA has disclosed to the complainant the total number of notifications it received every year from 2007 to 2018. And MHRA has disclosed the total number of notifications it received from each importer from 2007 to 2018.

40. In its initial submission MHRA noted that in their most recent request, the complainant has now requested the breakdown of names of importers for particular months and years. It said that if it were to

provide that information, the complainant would be able to map the supply chain of the products for each importer and it is this which MRHA considers to be commercially sensitive information. In effect MHRA would be providing the redacted information from column B of the spreadsheet supplied in reply to FOI 18/458.

41. MHRA said the [Human Medicines] Regulations [2012] require full disclosure of the supply chain to MHRA, to enable it to assess any notifications to import unlicensed medicines that it receives. Manufacturers and importers provide this information to MHRA on the understanding that it is held in confidence, given that, in effect, it provides information on the commercial arrangements that importers have.

42. The Commissioner understood that MHRA's position is not that the names of the importers is commercially sensitive per se, but that with the importers' names, together with other information already in the public domain, the complainant (or another person) would be able to map the supply chain of the [co-proxamol] products for each importer. It is the supply chain information which MHRA considers to be commercially sensitive.

43. The Commissioner had noted that, in FOI 18/458, MHRA had disclosed information about the importers in a spreadsheet but had withheld the importers' names. He queried why, if it were now to disclose the importers' names in that spreadsheet – which is the focus of the complainant's request – this would prejudice the importers' commercial interests any more than disclosing the remainder of the spreadsheet and the information subsequently disclosed in FOI 20/549 may (or may not) have already done.

44. The Commissioner discussed MHRA's submission with it in a telephone conversation on 23 June 2022 which MHRA followed up with a further submission on 26 July 2022.

45. MHRA explained that although individual supply chains have been disclosed to the complainant, the ownership of individual supply chains has not ie which importer used each supply chain to obtain its product. MHRA said that disclosing information about an importer's supply chain could commercially disadvantage that importer as it would allow their competitors to use the information to their own commercial advantage.

**1. Does the harm that MHRA alleges would, or would be likely, to occur if the withheld information were disclosed relate to the applicable interests within the relevant exemption?**

46. The requested information is associated with the supply chains through which various licenced importers obtain co-proxamol-containing products. As such the Commissioner is satisfied that the information is commercial in nature and relates to the applicable interest within section 43(2).

**2. Has MHRA demonstrated that some causal relationship exists between the potential disclosure of the information and the prejudice which the exemption is designed to protect?**

47. MHRA has advised that the Human Medicines Regulations 2012 requires an importer to disclose fully its supply chain to MHRA. It says that importers will provide it with commercial and scientific information in confidence and for the sole purpose of allowing MHRA to assess the requests [to import]. This regulatory information is provided to the MHRA in confidence as part of the regulatory decision making process. It allows for a risk based vetoing of the notifications to import unlicensed medicines. Where information is disclosed to MHRA for a particular purpose, it is bound by the common law duty of confidentiality not to use the information for a different purpose, or to disclose the information to other people without the company's explicit consent, unless required to do so by law or where there is an overriding public interest in disclosure. Manufacturers and importers provide this information on the understanding that MHRA will hold it in confidence.

48. MHRA says it cannot comply with the complainant's request as this would infringe on this duty to hold commercial, regulatory and scientific information of importers of unlicensed medicines confidentially.

49. As has been noted, it was not clear to the Commissioner why disclosing the names of the licensed importers of co-proxamol would, alongside the other supply chain information that has been disclosed, prejudice those importers' commercial interests. He asked MHRA to provide further explanation about this in correspondence dated 9 June 2022, in the telephone conversation and follow up correspondence on 23 June 2022 and again in correspondence to MHRA on 1 August 2022.

50. In these communications the Commissioner queried why now disclosing the importers' names being withheld from the disclosed spreadsheet would prejudice the importers' commercial interests any more than disclosing the remainder of the spreadsheet may (or may not) have already done. He wondered why now disclosing an importer's name potentially gave a competitor a particular advantage, any more than the competitor may have been advantaged through the rest of the supply chain information which has already been disclosed.

51. In response to the Commissioner's 23 June 2022 correspondence, MHRA's 26 July 2022 submission discusses the confidentiality of the information – the importers' names – but did not clearly address the Commissioner's specific query.

52. The Commissioner's correspondence of 1 August 2022 prompted MHRA to provide its fresh response to the complainant on 9 August 2022, a copy of which it sent to the Commissioner. That correspondence discusses confidentiality matters associated with section 41 and section 43 but, again, does not make a clear link between disclosing the importers' names and prejudicing the importers' commercial interests. MHRA did not suggest to the Commissioner that he could expect to receive any further submission from it which would address the specific question he had put to MHRA.

**Conclusion**

53. In his decision in FS50796228 the Commissioner instructed MHRA to disclose the names of licensed importers of co-proxamol. In response to the request discussed in that notice MHRA had disclosed the number of countries importing co-proxamol and the name and location (ie country) of the manufacturers who made and supplied co-proxamol to the UK. At the time of the decision in May 2019, other details about the importers' supply chains had not been disclosed and the Commissioner did not consider that disclosing the importers names would prejudice those importers' commercial interests.

54. MHRA disclosed the importers names but the importers were not linked to any particular supply chain. However, at the point of the current request, MHRA had disclosed information about the importers' supply chains in the spreadsheet discussed in this notice, as a result of other requests the complainant had submitted.

55. The Commissioner considers that he has given MHRA ample opportunity to make a clear case that, taking account of the wider circumstances in this case (ie that the importers' names in a particular context and other supply chain information that has been disclosed) disclosing the withheld information in the context of this request would or would be likely to now prejudice the importers' commercial interests. No such case has been made and the Commissioner has therefore not been persuaded that there is a causal link between disclosure and the envisioned prejudice.

56. Because he finds that the second of the criteria at paragraph 29 has not been met, it follows that the withheld information cannot engage the section 43(2) exemption. It is therefore not necessary to carry out the public interest test.

## Right of appeal

57. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

58. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

59. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

**Signed**

**Cressida Woodall**
**Senior Case Officer**
**Information Commissioner's Office**
**Wycliffe House**
**Water Lane**
**Wilmslow**
**Cheshire**
**SK9 5AF**