Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 23 May 2019

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 information from the Medicines and Healthcare Products Regulatory Agency (MHRA) about the importation of Co-proxamol. The MHRA disclosed the information under parts 1 and 2 of the request and also some of the information under part 3 but applied section 41 (Information provided in confidence) and 43 (Commercial interest) of the FOIA to withhold the names of the licenced importers.

2. The Commissioner's decision is that the MHRA has not sufficiently demonstrated that section 41 or 43 of the FOIA is engaged in relation to the information that has been withheld under part 3 of the request.

3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation.

    - Disclose the names of the licensed importers of Co-proxamol.

4. The public authority must take these steps 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.

Request and response

5. On 19 August 2018, the complainant wrote to MHRA and requested information in the following terms:

"1) How many countries supplied Co-proxamol to the UK from 1st January 2007 to the date of this request?

2) The name and country of the companies who manufactured and supplied Co-proxamol to the UK from 1st January 2007 to the date of this request?

3) The number and names of all licensed UK importers of Co-proxamol from 1st November 2015 to the date of this request?"

6. On 4 September 2018 the MHRA responded. In regard to part 1 of the request, it said it had applied section 43 of the FOIA to withhold this information. In regard to parts 2 and 3 of the request, it said it had disclosed the information in the attachment accompanying the response.

7. On 12 October 2018 the MHRA conducted a review and wrote to the complainant maintaining its position. The review however refers to section 43 of the FOIA being applied to withhold the information under part 3 and not part 1 of the request.

Scope of the case

8. On 24 October 2018 the complainant contacted the Commissioner to complain about the way his request for information had been handled.

9. During the course of the Commissioner's investigation the MHRA has confirmed that it has disclosed all the information requested under parts 1 and 2 of the request. It has since also released the number of licenced importers of Co-proxamol requested under part 3 of the request, and has applied section 41 and 43 of the FOIA to withhold the names of the licenced importers.

10. The Commissioner has considered whether the MHRA has correctly applied section 41 and/or 43 of the FOIA to withhold the names of the licenced importers of Co-proxamol under part 3 of the request.

Reasons for decision

Section 41 of the FOIA – Information provided in confidence

11. Section 41 of the FOIA provides that information is exempt from disclosure if it was provided to a public authority by another person and disclosing it would be an 'actionable' breach of confidence (e.g., the aggrieved party would have the right to take the authority to court as a result of the disclosure).

Was the information provided by another person?

12. The MHRA has explained that under the Human Medicines Regulations 2012 (the Regulations) unlicensed medicines (Co-proxamol) being purchased to be supplied to another person (clinics, Trusts etc) must be imported via a licenced importer that holds a Wholesale Dealers Licence. It said that the withheld information was obtained by it because Schedule 4 of the Regulations requires importers to complete a notification form giving prescribed particulars, including; the importer's name, medicine, manufacturer (supplier), manufacturing country etc when notifying the MHRA of an intended import for a client in the UK. The Commissioner is satisfied that the information was therefore provided by another person.

Would disclosure constitute an actionable breach of confidence?

13. In considering whether disclosure of information constitutes an actionable breach of confidence the Commissioner will consider 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.

Does the information have the necessary quality of confidence?

14. Information will have the necessary quality of confidence if it is more than trivial and if it is not otherwise accessible.

15. The Commissioner notes the complainant's view that since becoming an unlicensed medicine the price of Co-proxamol has risen in recent years and is concerned about the cost implications on the NHS meaning that it can no longer afford to prescribe the medication to patients. The Commissioner has reviewed the withheld information and notes it is only held by the MHRA because of the requirement of Schedule 4 of the Regulations. She has seen no evidence that the withheld information has been put in the public domain. The Commissioner has therefore determined that the information is not trivial and is satisfied that it would only be accessible by the MHRA.

Was the information imparted in circumstances importing an obligation of confidence?

16. Even if information is to be regarded as confidential, a breach of confidence will not be actionable if it was not communicated in circumstances that created an obligation of confidence. An obligation of confidence may be expressed explicitly or implicitly.

17. The information was obtained from the importers by the MHRA as a requirement of the Regulations. The MHRA says its primary aim is to safeguard public health and information provided under statuary provisions which further those aims should not be used for other purposes. The Commissioner is satisfied that the names of the importers can be said to be have been imparted in circumstances importing an implied obligation of confidence, since the information is not trivial, has only been obtained in order to fulfil the MHRA's statutory duty in relation medicine regulation and would only be accessible by the MHRA.

Detriment to the confider

18. Developments in case law have established that information about individual's private and personal life can be protected by the law of confidence, even if disclosure would not result in any tangible loss to the confider. If the requested information is commercial in nature then the disclosure will only constitute a breach of confidence if it would have a detrimental impact on the confider. The authority will be expected to put forward an explicit case for detriment. Usually the detriment to the confider in such cases will be a detriment to the confider's commercial interests.[1]

[1] https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-confidence-section-41.pdf

19. The MHRA said that disclosing the withheld information could prejudice the commercial interest of the importers by allowing competitors to gain an advantage in the market resulting in claims being made by the importers against the MHRA. It says that a valuable business asset of importers is their database of customers, suppliers, manufacturers and information about their products. Disclosing the withheld information would enable competitors to link importers to contracts with specific suppliers and by doing this competitors could ascertain what the importers 'are doing' and where they are obtaining their supplies.

20. It said that competitors could use this information to go directly to the importers sources and construct deals with suppliers to compete with, undercut and/or disrupt importers. The MHRA said it had previously been made aware of the 'sensitivities' of importers about disclosing data relating to their products/suppliers, this has resulted in the MHRA's quarterly reports no longer identifying what products are being imported by specific importers and products only being identified by their generic and not by brand names. In regard to the complainant's view about the withheld information informing public debate about the cost of Co-proxamol, the MHRA explained that 2.2 and 2.3 of the MHRA's Guidance Note 14 makes it clear that the responsibility for the prescription lies with the medical specialist and only the special clinical needs of the patient are taken into account. It said that the cost of the medication is not taken into account when prescribing and the pricing is not in the MHRA's functions.

21. The Commissioner notes that the name of the unlicensed medicine (Co-proxamol) is stated in the request. She also notes that the MHRA has already disclosed the names of the importer's suppliers (manufacturers) and the manufacturing countries in response to part 2 of the request. She also notes that conducting a basic internet search of both the importers and suppliers company names locates their company information / websites that mention their pharmaceutical supply services. This information is already in the public domain for any of its competitors to obtain. In the absence of the importers identity, the importers customers and competitors can still use the information already disclosed to contact the importers suppliers directly.

22. The Commissioner acknowledges the MHRA's comments about how the information could be used by competitors, she is not however convinced that disclosing the importers names without other specific commercial information about existing importer/supplier relationships, e.g. contracts, price lists, etc that competitors could use to meaningfully inform and impact negotiations will result in competition or disruption to the importers or enable competitors to undercut them.

23. She also notes that information about the identity of the importer's customers (clinics, Trusts etc) has not been requested, and cannot see how the withheld information could be used by competitors (even if they managed to form relationships with the same suppliers, they do not have access to the importer's client base) to undercut importers. She also understands that the requirements of the Regulations mean that the importers customers cannot import medicines directly themselves (they must use a licenced importer).

24. The Commissioner further notes that the MHRA has failed to confirm whether any of the importers that raised previous sensitivities about products/suppliers being disclosed are the same as those listed in the withheld information (in regard to Co-proxamol) and what those specific 'sensitivities' are, instead it only said it no longer identifies products imported by *specific* (not all) importers in its quarterly reports. She also notes the requirements set out in 2.2 and 2.3 of Guidance Note 14 and the MHRA's comments that only the special clinical needs of the patient and not the cost of medicines should be taken into account when prescribing medicines.

25. The Commissioner therefore considers that the MHRA has not provided any tangible evidence that disclosure of the withheld information will cause detriment to the importers' commercial interests and that the exemption at section 41 of the FOIA has not been engaged. She will now go on to consider the application of section 43 of the FOIA.

Section 43 of the FOIA – Prejudice to commercial interests

26. Section 43 of the FOIA provides that if the disclosure of information would prejudice the commercial interests of any person including the public authority who holds the information, then the information is exempt from disclosure. This is a prejudice-based exemption and is subject to the public interest test.

27. In order for section 43(2) to be engaged the Commissioner considers that 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 was disclosed has to relate to the applicable interests within the relevant exemption.

28. 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.

29. 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. In relation to the lower threshold, the Commissioner considers that the chance of prejudice occurring must be more than a hypothetical possibility; rather there must be a real and significant risk. With regard to the higher threshold, in the Commissioner's view this places a stronger evidential burden on the public authority. The anticipated prejudice must be more likely than not.

30. The MHRA has confirmed that in its view disclosing the names of the importers to the public would (as opposed to would be likely to) prejudice the importers commercial interests.

31. It has then referred the Commissioner to its previous arguments used in support of its application of section 41, namely that disclosure would enable competitors to link the importers to contracts with specific suppliers and in doing so enable them to ascertain 'what the importers are doing' and where they are obtaining their supplies. This information would then be used to undercut and/or disrupt importers. In the MHRA's view disclosing the information would therefore be likely to significantly impact the importers ability to effectively compete with its competitors in the medicines supply market.

32. The Commissioner is of the same view as detailed in paragraphs 21 -23 (above) with regard to section 41, she is not convinced that disclosing the importers names without other specific commercial information about importer/supplier relationships e.g., contracts, price lists, etc that competitors could use to meaningfully inform and impact negotiations will result in competition or disruption to the importers or enable competitors to undercut them. She understands that information about the identity of the importer's customers (clinics, Trusts etc) has not been requested, and cannot see how the withheld information could be used by competitors (even if they formed relationships with the same suppliers, they do not have access to the importer's client base) to undercut importers. She is also mindful that in the absence of the importers names, the identity of the suppliers has already been disclosed and that company information about both the importers and suppliers pharmaceutical supply services is otherwise already available on the internet (on their websites). This information can therefore be used by the importers customers and competitors to contact the suppliers directly in respect of the supply of unlicensed medicines. She also understands that the requirements of the Regulations mean that the importers customers cannot in fact import medicines directly themselves and must use a licenced importer that holds a wholesale dealers licence. She also notes that the MHRA has failed to confirm whether any of the importers that raised previous sensitivities about

products/suppliers being disclosed are the same as those listed in the withheld information (in regard to Co-proxamol) and what those specific 'sensitivities' are, instead it only said it no longer identifies products imported by *specific* (not all) importers in its quarterly reports.

33. The Commissioner considers in order for the exemption to be engaged, it must be shown that the disclosure of specific information will result in specific prejudice to one of the parties. In demonstrating prejudice, an explicit link needs to be made between specific elements of withheld information and specific prejudice which disclosure of these elements would cause.

34. The arguments provided do not demonstrate that prejudice to the commercial interests of any party would occur. Therefore the engagement of the exemption falls at the first stage.

35. The Commissioner has concluded that the MHRA has not demonstrated to the required standard that it had correctly engaged the exemption at section 43(2) of the FOIA. Consequently it is not necessary for the Commissioner to consider the public interest test in this case.

Right of appeal

36. 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: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

37. 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.

38. 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 .....

Andrew White
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF