Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 16 October 2018

Public Authority: NHS Commissioning Board (NHS England)
Address: 4N22 Quarry House
Quarry Hill
Leeds
LS2 7UE

Decision (including any steps ordered)

1. The complainant has requested the patient access schemes/ commercial access agreements for two specified drugs. NHS England withheld the requested information under section 43(2) FOIA.

2. The Commissioner considers that NHS England has correctly applied section 43(2) FOIA to the withheld information.

3. The Commissioner requires no steps to be taken.

Request and response

4. On 15 December 2017 the complainant requested information of the following description:

"In line with FOIA please provide all the versions of the patient access schemes / commercial access agreements (submitted, currently active, withdrawn or no longer active) for the following drugs:

Tarceva (erlotinib) both in first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer (TA258) and non-small-cell lung cancer that has progressed after prior chemotherapy (TA374)

Keytruda (pembrolizumab) both in 8222;advanced melanoma after disease progression with ipilimumab (TA357), Advanced melanoma not previously treated with ipilimumab (TA366) and PD-L1 positive non-small-cell lung cancer after chemotherapy (TA428)."

5. On 2 January 2018 NHS England responded. It denied holding the requested information.

6. The complainant requested an internal review on 1 February 2018. NHS England sent the outcome of its internal review on 7 February 2018. It revised its position. It confirmed that it did hold some information falling within the scope of the request but that this was exempt from disclosure under section 43(2) FOIA. This information was one commercial access agreement (CAA) relating to Keytruda (pembrolizumab).

Scope of the case

7. The complainant contacted the Commissioner on 17 February 2018 to complain about the way his request for information had been handled.

8. The Commissioner has considered whether NHS England was correct to apply section 43(2) to the withheld information.

Reasons for decision

Section 43 – commercial interests

9. Section 43(2) says that information is exempt information if its disclosure under the FOIA would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it). Trade secrets are one example of commercial interests but the concept is far wider. Commercial interest relates to a person's ability to participate competitively in a commercial activity ie the purchase and sale of goods or services.

10. In order for the exemption to be engaged NHS England would need to demonstrate that disclosing the information would result in some identifiable commercial prejudice which would, or would be likely to, affect one or more parties. Section 43(2) is a qualified exemption and is therefore subject to the public interest test.

11. NHS England has confirmed to the complainant that it holds information falling within the scope of his request. It has provided the information to the Commissioner and she has reviewed it. It is a CAA for patient access to a particular drug, pembrolizumab. The Commissioner is satisfied that the withheld information relates to a

commercial activity i.e. the supply of a particular drug for patient access in the UK and falls within the scope of the exemption.

Likelihood of prejudice occurring

12. The ICO has been guided on the interpretation of the phrase 'would, or would be likely to' by a number of Information Tribunal decisions. The Tribunal has been clear that this phrase means that there are two possible limbs upon which a prejudice based exemption can be engaged; ie either prejudice 'would' occur or prejudice 'would be likely to' occur.

13. With regard to 'would be likely to prejudice', the Information Tribunal in John Connor Press Associates Limited v The Information Commissioner (EA/2005/0005) confirmed that 'the chance of prejudice being suffered should be more than a hypothetical possibility; there must have been a real and significant risk' (Tribunal at paragraph 15).

14. With regard to the alternative limb of 'would prejudice', the Tribunal in Hogan v Oxford City Council & The Information Commissioner (EA/2005/0026 & 0030) commented that 'clearly this second limb of the test places a stronger evidential burden on the public authority to discharge' (Tribunal at paragraph 36).

15. NHS England considers that both it's and a third party contractor's (MSD) ability to participate competitively in a commercial activity would be severely prejudiced if the information requested was disclosed. It considers that the prejudice would be likely to occur.

16. MSD considers that "manufacturers…engage actively on the basis of assured confidentiality with bodies such as NICE and NHS England with the expectation that mutual confidentiality is assured…any disclosure of such sensitive commercial and confidential information would cause irreparable harm to MSD". NHS England provided the Commissioner with a letter from MSD confirming its position.

17. MSD has explained that it is able to bring innovative pharmaceutical products to the UK market, often as a country of first launch choice, because there is notional pricing freedom in the market. MSD can therefore set its list price with relative freedom and notification to the Department of Health and Social Care. This public list price, is then used as the publicly available price for a pharmaceutical product. This public list price is then negotiated in good faith, under duties of confidentiality with NICE and NHS England, supported by a variety of cost effectiveness, clinical background information and outcomes data; in order for NICE and MSD to negotiate and agree a discounted price, considered to be cost effective for NHS England.

18. MSD has also said that disclosure would enable its competitors to gain a significant and unfair competitive advantage and commercial benefit, by being able to incorporate within their strategic planning and pricing submissions, the confidential and commercially sensitive information provided to NHS England, adjust their business plan accordingly (with background knowledge of MSD's business plan in hand) and could adjust their financial planning and structure accordingly. MSD therefore has a legitimate expectation that this information would not be disclosed. MSD said that the CAA provides detail on a range of licensed indications for Keytruda, so the damage will not only be limited to the first line NSCLC, but would be felt across the entire range of indications for Keytruda.

19. NHS England also considers that it's commercial interests would be prejudiced by the disclosure of this information. A significant part of NHS England's role is to negotiate commercial agreements with suppliers, like MSD, so that patients can access drugs which are cost-effective. NHS England is concerned that disclosure of the withheld CAA could lead to MSD withdrawing from the agreement or varying its terms to make the drug more expensive. It is possible that any revised pricing could make the drug too expensive for NHS England to purchase. In that case, it would result in the population covered by the agreement losing access to pembrolizumab. Accordingly, disclosure of the agreement would clearly prejudice NHS England's commercial interests as it would not be able to purchase pembrolizumab at the discounts currently on offer and on a worst case scenario, possibly not at all, causing severe prejudice to patient care. NHS England would also not be able to purchase this drug from other sources as MSD is the sole supplier.

20. It said that on a wider scale, should this information be disclosed under FOIA, MSD has made it clear in their letter, which was provided to the Commissioner, that "disclosure will very likely create distrust between the industry and NHS England". This is a point with which NHS England agrees. It considers that NHS England's ability to make future commercial deals would be hampered by the distrust this disclosure would be likely to create.

21. Disclosure, and the resultant distrust, would be likely to dissuade pharmaceutical companies from engaging openly with NHS England in respect of their products. This engagement allows NHS England to negotiate on pricing, and is predicated on the understanding that agreed pricing/reimbursement mechanisms will be kept confidential. The disclosure of the agreement, which is highly confidential and sensitive and which has been confidentially negotiated regarding

pricing and reimbursement, would lead to a perception in the marketplace that NHS England will not preserve confidentiality. To disclose this information would therefore be likely to jeopardise NHS England's ability to secure best value for money for the NHS, significantly prejudicing its commercial interests.

22. MSD considers it is fundamental for manufacturers to be able to engage with NHS England openly but pursuant to confidentiality obligations when dealing with the supply of products. This is to ensure competitors do not gain an unfair advantage and to also benefit NHS England with regards to negotiated discounts. If confidentiality could not be assured by NHS England, suppliers would operate in an entirely different way which could ultimately result in NHS England's commercial interests being prejudiced by either losing access to newer and/or innovative pharmaceutical products or facing higher prices for access to those treatments, which will in turn result in a detriment to patient care. A fundamental principle of the NHS is its commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population. Delivery of this principle will be prejudiced if NHS England releases information which could prejudice its interests and those of its suppliers.

23. The complainant has argued that NHS England's negotiating position would be stronger if the requested information were disclosed. He has stated that, "It can be argued that the purchasing power of NHS England is currently large, but that power would never compare to the purchasing power they actually get when they will practically represent nearly the whole world of interested public and private payers, health service providers, companies and the competent public." He has also said that, "The UK pharma market is too large for the global pharma companies not to enter it." He therefore considers that disclosure of the withheld information would result in NHS England having a stronger bargaining position and that MSD would not withdraw from the UK market, given its size, should the withheld information be disclosed.

24. In this case NHS England has explained that MSD is the only current supplier of this particular drug to the UK. The Commissioner does not therefore accept that disclosure of the withheld information would be likely to prejudice the commercial interests of NHS England or MSD in terms of the supply of this particular drug in the UK. There are no other possible suppliers so MSD does not have any competitors in this context and NHS England does not have any alternative suppliers to negotiate with.

25. However disclosure of MSD's CAA with the UK would be likely to provide a commercial advantage to its competitors internationally, as they would have access to detail on a range of licensed indications for Keytruda, so as explained above the damage would not only be limited to the first line NSCLC, but would be felt across the entire range of indications for Keytruda. MSD would not have the same access to competitor's information thereby distorting the level playing field. Additionally the Commissioner accepts that disclosure of the detail of MSD's agreement with the UK would be likely to provide a commercial advantage to other countries to which MSD supplies this drug to as it would reveal the discounted rate negotiated in the UK. This would be likely to assist other international health organisations in their own negotiations with MSD. The Commissioner also accepts that based upon the evidence presented by MSD, disclosure may dissuade it and other pharmaceutical companies from engaging openly with NHS England in respect of their products and agreeing discounted rates for fear this would be disclosed into the public domain. Whilst this may not mean MSD would withdraw from the UK market, the distrust felt by it and other pharmaceutical companies would be likely to hinder NHS England's negotiating position and its ability to secure best value for money.

26. In this case, the Commissioner finds that NHS England has demonstrated that disclosing the information would be likely to prejudice its own and MSD's commercial interests and that section 43(2) is engaged.

27. The Commissioner has therefore gone on to consider the public interest test in this case.

Public interest test

Public interest in favour of disclosure

28. NHS England acknowledged that there is a generic public interest in openness and transparency.

Public interest in favour of maintaining the exemption

29. The agreement has been negotiated on the condition that confidentiality is maintained in order to allow access to pembrolizumab on mutually agreeable terms for the ultimate benefit of patients.

30. On a wider scale, the need to maintain confidentiality over negotiations with suppliers allows NHS England to obtain quicker access to new products and at the best price for the benefit of patients. If the withheld information were disclosed, it would lead to a lack of confidence by suppliers in engaging with NHS England and/or NICE, a potential lack of investment by suppliers/manufacturers in England which will mean more limited and/or delayed access to new products and a more difficult negotiating process with suppliers only wanting to provide limited access to information than is presently the case. Accordingly, the public interest is clearly served by maintaining the exemption not only to safeguard this particular agreement but to also safeguard the ability of NHS England to negotiate with commercial organisations around the supply of products to patients using the NHS.

Balance of the public interest

31. The Commissioner considers that there is a public interest in NHS England operating openly and transparently.

32. The Commissioner considers there is a strong public interest in protecting NHS England's ability to negotiate with commercial organisations around the supply of products to patients using the NHS and to secure best value for money. The NHS is under significant pressure to stretch budgets to enable various medicines to be available in the UK. If information is disclosed which would be likely to make the negotiation process more difficult or pharmaceutical companies less willing to agree discounted rates, this would significantly hinder NHS England's negotiating position in this area which would not be in the public interest.

33. The Commissioner also considers that there is a public interest in not distorting the commercial playing field, by disclosing the detailed commercial arrangements of one party to the advantage of its competitors or other potential customers.

34. On balance the Commissioner considers that the public interest in favour of disclosure is outweighed by the public interest in maintaining the exemption in this case.

Right of appeal

35. 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

36. 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.

37. 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 .....

Pam Clements
Group Manager

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