Reference: IC-195519-T0X4

Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**21 April 2023**
Public Authority:	**Royal Free London NHS Foundation Trust**
Address:	**Anne Bryans House** **77 Fleet Road** **London** **NW23 2QH**

Decision (including any steps ordered)

1. The complainant has requested information about a product manufactured at the Royal Free London NHS Foundation Trust's ("the Trust") Centre for Cell, Gene and Tissue Therapeutics. The Trust provided information for request [3] and stated no information was held for request [6] but refused the remaining requests under section 43(2) of FOIA.

2. The Commissioner's decision is that the Trust has correctly engaged the exemption in relation to requests [4] and [5] and the public interest favours maintaining the exemption and withholding the information. In relation to requests [1], [2] and [7] the Commissioner has found the section 43(2) exemption is not engaged.

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

    - Disclose the information requested at parts [1], [2] and [7].

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 17 June 2022 the complainant wrote to the Trust and requested information in the following terms:

> "My FOI request concerns the advanced therapy medicinal product (ATMP) DCVax-L that is/was manufactured by the company Advent Bioservices (previously called Cognate Bioservices) that is/was renting lab facilities at the Royal Free's Centre for Cell, Gene and Tissue Therapeutics (CCGTT).
>
> DCVax-L was being manufactured for participants in a clinical trial sponsored by Northwest Biotherapeutics (https://clinicaltrials.gov/ct2/show/NCT00045968) and also on a compassionate use basis for patients who were not participating in the clinical trial.
>
> The manufacture of DCVax-L requires tumour lysate derived from patients' brain tumour tissue, and dendritic cells derived from the patients' peripheral blood mononuclear cells (PBMCs).
>
> My questions are as follows:
>
> [1] Under which HTA licence(s) was the brain tumour tissue procured, stored and processed (to generate tumour lysate)?
>
> [2] Under which HTA licence(s) was the PBMCs procured, stored and processed?
>
> [3] Under which MHRA Specials licence was the DCVax-L released for patients being treated under compassionate use?
>
> [4] From Jan 2013 to present day, how many batches of DCVax-L have been manufactured in the Royal Free's CCGTT? Please consider a batch to be the total number of doses manufactured for an individual patient.
>
> [5] Of the total number of batches manufactured between Jan 2013 and present day, how many were manufactured for clinical trial NCT00045968, and how many for patients on a compassionate use basis?
>
> [6] How much were patients charged (in £) for receiving DCVax-L under compassionate use?
>
> [7] From Jan 2013, how much did the Royal Free charge (in £) Advent Bioservices for use of the Royal Free's facilities?"

6. The Trust responded on 18 July 2022. For [3] it provided the licence number and for [6] it stated the information was not held. For all other

parts of the request the Trust stated that the information was held but was exempt under section 43(2) of FOIA.

7. Following an internal review the Trust wrote to the complainant on 20 October 2022. It stated that it upheld its position that the information requested at parts [1], [2], [4], [5] and [7] of the request was exempt under section 43(2).

Reasons for decision

8. Section 43(2) FOIA exempts information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person (ie an individual, a company, the public authority itself or any other legal entity). In order for such information to be exempt, a public authority must show that, because it is commercially sensitive, disclosure of it would, or would be likely to, prejudice the person's commercial interest. The exemption is qualified, so where the exemption is engaged it is then necessary to apply a public interest balancing test.

9. In this case the Trust has argued that disclosure of the information would prejudice the commercial interests of Advent Bio. The Trust consulted with Advent on receipt of the request and during the Commissioner's investigation.

10. The arguments presented explain why Advent considers the information to be commercial in nature and why there would be prejudice to its commercial interests should it be disclosed.

Request [1]

11. This request asked for the Human Tissue Authority (HTA) licence(s) under which brain tumour tissue was procured and processed. Advent argued that obtaining tumour tissue is essential for its business as DCVax-L (a vaccine that uses patient's immune cells to target cancer) cannot be manufactured without a tumour tissue sample and there is competition for tumour tissue. It argues that revealing the sources would give an unfair advantage to competitors who could then be competing for the same sources.

12. Advent further argues that, to be usable, the tumour tissue must be handled correctly by the hospital from which it was obtained and Advent Bio has had to train the sites to do this correctly. Revealing the sources from which Advent has obtained tumour tissue would enable competitors to take advantage of Advent having already trained those sites.

13. The Commissioner notes the request asks under which HTA licence(s) the activity was undertaken. The answer to this request should be a

simple case of providing the licence number which in itself does not seem to be commercial information. The complainant argues that the licence number is needed to be able to search for the relevant inspection report from any HTA inspection that might have taken place and any such report would be in the public domain.

14. The HTA will undertake inspections where it needs to satisfy itself that a designated individual is a suitable person to supervise the activity that is authorised by a licence. An inspection will ensure that staff working under licence are suitable, practices used when carrying out the activity are suitable and licence conditions are met. Inspection reports are then published on the HTA website. These can be searched either by licence number or by establishment.

15. The Commissioner notes that if an inspection has occurred and the licence number is searched this will bring up the report and this will name the body involved ie the Trust or Hospital. The question for the Commissioner is if the licence number reveals the Trust or Hospital from which Advent procured tumour tissue would this be commercially prejudicial to Advent? Advent's argument is that it has invested time in training the sites it uses to handle tissue samples appropriately and as there is competition for tumour tissue samples revealing the sources it uses and has invested training in would put them at a disadvantage by allowing for more competition.

16. The Commissioner is not convinced that disclosing the licence number in this case would be commercially prejudicial to Advent. Whilst it is appreciated that there is demand for tumour tissue samples revealing where Advent obtains some of its samples from, it is not in itself likely to be commercially prejudicial. It is quite likely that any site that is licenced to process tissue samples will be known to the competitors, what may not be known is if that particular site is used by Advent to procure samples. The knowledge of this fact on its own is not likely to be commercially disadvantageous to any party as the frequency at which samples are available is not known or the terms under which Advent obtains samples from the site.

17. As such the Commissioner does not consider that disclosing the licence number would have the prejudicial effect envisaged by Advent and the exemption is not engaged in relation to part [1] of the request.

Request [2]

18. As with [1] this request concerns the HTA licence under which peripheral blood mononuclear cells (PBMCs) were procured and processed. The arguments from Advent are largely similar as with [1] in that it states the blood draw procedure takes time and DCVax-L products cannot be manufactured without obtaining the necessary immune cells via

apheresis procedures. Advent states there is a shortage of apheresis capacity in the UK and it has worked to develop arrangements with certain institutions to access slots for apheresis procedures and knowledge of these arrangements could give competitors an advantage in trying to obtain these slots for themselves.

19. For the same reasoning as [1] the Commissioner does not consider that disclosing the licence number(s) would have the prejudicial effect envisaged by Advent and the exemption is not engaged in relation to part [2].

Request [4]

20. This request asked for the number of batches of DCVax-L manufactured in the Trust's Centre for Cell Gene and Tissue Therapeutics (CCGTT). The request specified that a "batch" should be taken to mean the total number of doses manufactured for an individual patient.

21. Advent argued that the process of manufacturing living cell products is complex and several other companies have been experimenting with different formulas and processes to determine how to manufacture/optimise cellular products. It states that whilst some companies can only produce single doses, Advent has developed methods to produce multiple years of doses in a single manufacturing cycle which puts it at a competitive advantage. This has led to competitors being very keen to find out information about Advent's manufacturing process and, to date, Advent has not revealed publicly what numbers of batches it has produced for a given number of patients, nor how many doses its manufacturing process produces.

22. Advent considers that providing this information in response to a FOIA request would enable competitors to "reverse engineer" the manufacturing process and work out key information about Advent's optimized processes for manufacturing these products. That would significantly damage the competitive advantage that Advent has worked for many years to develop.

23. The Commissioner accepts that this information is commercial in nature and that Advent has developed processes that have put it at a commercial advantage over its competitors. The fact the information is not publicly known is of significance as it demonstrates that this is information that could be useful to competitors and the possibility of it being used to 'reverse engineer' the process cannot be dismissed, no matter how likely or unlikely. If disclosing the information at this part of the request may lead to competitors being able to work out anything to do with Advent's manufacturing process then it is reasonable to conclude that this would be likely to prejudice Advent's commercial interest and the Commissioner finds the exemption is engaged in

relation to part [4] of the request. He will go on to consider the public interest later.

Request [5]

24. This request sought to find out how many of the batches manufactured since January 2013 were for a specific clinical trial and how many were for compassionate use.

25. Advent argued similarly to request [4] in that it considered the breakdown of how many batches were for clinical trial and how many for compassionate use would reveal sensitive information about Advent's proprietary research and development activities. The Commissioner was also provided with more specific details relating to the manufacturing process that have not been included here.

26. For the same reasoning as for [4] the Commissioner accepts the exemption is engaged in relation to the information requested at [5] and the public interest test will go on to be considered later.

Request [7]

27. This request asked for the amount the Trust charged Advent for use of its facilities. The Trust and Advent state that this is specified in a commercial contract and is therefore commercially confidential information. It is argued that disclosing this information might allow competitors to obtain a competitive advantage over Advent and the Trust in future contractual negotiations. Advent further states that for cell therapy products a specialised type of manufacturing facility is needed, different from manufacturing facilities for other types of medical products. As such the manufacturing facilities costs comprise a major portion of the overall product costs for a cell therapy such as DCVax-L. Thus revealing the amounts paid to the Trust by Advent for use of its facilities could enable competitors to 'reverse engineer' key information about Advent's costs and margins.

28. The Commissioner appreciates that information that might reveal anything about the proprietary research and development process of the manufacture of DCVax-L is likely to be commercially sensitive. However, he is not minded to accept that the amount Advent has paid the Trust for use of its facilities is likely to prejudice Advent's commercial interests.

29. The Commissioner notes that if it is known how much the overall production cost of products is then knowing the cost paid by Advent for use of the facilities at the Trust would allow someone to know the remaining amount of the overall production cost minus this amount. What the Commissioner is not convinced by is how knowing this could allow competitors to 'reverse engineer' this to glean an insight into

Advent's costs and margins. There will be a number of other overheads and costs beyond the manufacturing facility costs that will make up the overall product cost and without any breakdown of the costs it is difficult to see how this information could be of use to competitors or place Advent at a commercial disadvantage. Similarly, knowing how much is paid to the Trust alone would not necessarily disadvantage the Trust or Advent in future contract negotiations – the contract will contain information on the services and facilities included and this may well be bespoke to Advent and their needs. Again, without any further breakdown of the cost, or evidence to suggest there are impending contract negotiations or tendering exercises, the Commissioner does not consider an overall figure is likely to be prejudicial to either party. As such the Commissioner does not consider the information at [7] has been shown to engage the section 43(2) exemption and this information should now be disclosed.

Public interest test

30. As the Commissioner has found the section 43(2) exemption is engaged in relation to requests [4] and [5] he has now gone on to consider the public interest in this information.

31. The Trust acknowledges the public interest in it being open, transparent and accountable for the spending of public money and how it awards contracts to private sector companies. However it argued the public interest in withholding information that would negatively affect Advent's ability to negotiate or compete in a commercial environment was greater.

32. With specific regard to request [4] and [5] the complainant argued:

"Given that cell manufacturing facilities in an NHS hospital were being reserved for the exclusive use of a US company, I believe it is in the public interest for the Royal Free to reveal how many batches of the cell therapy were being manufactured on a not-for-profit basis (for the clinical trial) and how many were being manufactured under compassionate use to patients who were paying for the treatment."

33. The complainant has also pointed to a research article published in November 2022[1] in which it indicates that no manufacturing of DCVax-L for clinical trial was undertaken by any UK contractor. As such the complainant argues the Trust should have stated the number of batches manufactured in their CCGTT for the clinical trial was zero.

34. They argue the Trust it attempting to conceal the fact that no batches od DCVax-L were manufactured at the CCGTT for clinical trial and that, if this is the case, shareholder funds were transferred to Advent's facility

[1] https://jamanetwork.com/journals/jamaoncology/fullarticle/2798847

in the Trust's CCGTT without adequate justification. Conversely if a few batches were made for compassionate use this would raise concerns as the complainant states the CCGTT did not have an appropriate licence from the HTA.

35. In short much of the complainant's concerns stem from the fact that Advent was renting space in the Trust's CCGTT from 2015 and in this time money was transferred from the US company Northwest Biotherapeutics (NWBO) to Advent to pay for the manufacturing costs of DCVax-L. The complainant states there is evidence that little to no DCVax-L was actually manufactured at the CCGTT and that if this is the case shareholder funds were spent for no reason and there are suggestions that conflicts of interest may have contributed to the misappropriation of funds. As such the complainant believes the information should be disclosed to allow NWBO shareholders and DCVax-L patients full access to information.

36. The Commissioner has considered the arguments from both parties and considers that in accepting there is a likely prejudice to the commercial interests of Advent in disclosing the number of batches of DCVax-L that were manufactured (both in total and broken down for clinical trial/compassionate use) he also acknowledges there is a public interest in withholding this information as it may lead to knowledge of Advent's proprietary manufacturing processes and insight into their processes and capacity that was otherwise not known at the time of the request.

37. The Commissioner appreciates the complainant has concerns that shareholder funds have been sent to Advent to manufacture a product and that they need to know if any batches were actually manufactured and for what purpose to ensure that funds were appropriately used. It is not for the Commissioner to comment on any perceived wrongdoing by NWBO; he must consider the wider public interest in the disclosure of this information and he is not convinced there is significant public interest in knowing how many batches of DCVax-L were produced in the CCGTT that would outweigh the public interest in withholding the information and avoiding any damage to the commercial interests of Advent.

38. For the above reasons, the Commissioner is satisfied that section 43(2) of FOIA applies in relation to requests [4] and [5] and the public interest rests in maintaining the exemption.

39. However, the Commissioner has not found the exemption to be engaged in relation to request [1], [2] and [7] and the Trust should now disclose this information.

Right of appeal

40. 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

41. 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.

42. 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 .....

Jill Hulley
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