Investigation of a complaint against Belfast Health & Social Care Trust

Report Reference: 202001645

The Northern Ireland Public Services Ombudsman
33 Wellington Place
BELFAST
BT1 6HN
Tel: 028 9023 3821
Email: nipso@nipso.org.uk
Web: www.nipso.org.uk
@NIPSO_Comms

The Role of the Ombudsman

The Northern Ireland Public Services Ombudsman (NIPSO) provides a free, independent and impartial service for investigating complaints about public service providers in Northern Ireland.

The role of the Ombudsman is set out in the Public Services Ombudsman Act (Northern Ireland) 2016 (the 2016 Act). The Ombudsman can normally only accept a complaint after the complaints process of the public service provider has been exhausted.

The Ombudsman may investigate complaints about maladministration on the part of listed authorities, and on the merits of a decision taken by health and social care bodies, general health care providers and independent providers of health and social care. The purpose of an investigation is to ascertain if the matters alleged in the complaint properly warrant investigation and are in substance true.

Maladministration is not defined in the legislation, but is generally taken to include decisions made following improper consideration, action or inaction; delay; failure to follow procedures or the law; misleading or inaccurate statements; bias; or inadequate record keeping.

The Ombudsman must also consider whether maladministration has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. A remedy may be recommended where injustice is found as a consequence of the failings identified in a report.

Reporting in the Public Interest

This report is published pursuant to section 44 of the 2016 Act which allows the Ombudsman to publish an investigation report when it is in the public interest to do so.

The Ombudsman has taken into account the interests of the person aggrieved and other persons prior to publishing this report.

TABLE OF CONTENTS

Page

Case Reference: 202001645
Listed Authority: Belfast Health & Social Care Trust

SUMMARY

I received a complaint about the actions of the Belfast Health & Social Care Trust (the Trust). The complainant raised concerns about the length of time it took to procure specialist medicine to treat his wife's (the patient) condition.

I considered whether the Trust's actions to procure and facilitate transport of the medicine were reasonable. My investigation examined the Trust's actions to put in place relevant safeguards to store and handle a new unlicensed medicine, and its actions to facilitate the transport of the medicine through a third party logistics company.

It is evident to me that the complainant would have found the patient's deterioration and eventual death extremely distressing, especially given what appeared to be the inexplicable delay in transporting the medicine between Edinburgh and Belfast. However, my investigation found that the Trust's efforts to obtain and transport the medicine were reasonable and appropriate.

I did not uphold this complaint.

THE COMPLAINT

1. The complainant raised concerns about the actions of the Belfast Health and Social Care Trust (the Trust) in relation to the length of time it took to procure specialist T cells[1] to treat his wife's (the patient) condition.

Background

2. In September 2020 the patient was diagnosed with extranodal natural killer/T-cell lymphoma (ENKTL) - associated haemophagocytic lymphohistiocytosis (HLH)[2], which has a high mortality rate. ENKTL is an aggressive non-Hodgkin lymphoma[3] that is closely associated with the Epstein-Barr virus (EBV)[4].

3. The Trust treated the condition with chemotherapy and donor stem cell therapy in March 2021. Initially, the patient appeared to respond to treatment; however, follow up tests found a recurrence of EBV DNA in her blood on 20 April 2021. Her EBV levels continued to rise and the Trust admitted her to Belfast City Hospital (BCH) on 7 May for further investigation and management. The Trust treated the patient with high dose steroids for HLH and immunoglobulin[5] for EBV infection. The patient's EBV levels began to fall on 17 May 2021; however, they rose again on 23 May 2021.

4. As the previous treatments had not worked, the Trust made the decision to treat the patient using EBV-specific cytotoxic T-lymphocytes (EBV-CTLs)[6], which was an unlicensed medicine[7]. On 26 May 2021 the Trust submitted a request for EBV-CTLs to the Scottish National Blood Transfusion Service (SNBTS) which manages the CTL bank in Edinburgh. The CTL bank supplies transplant centres in UK with EBV CTLs. The EBV-CTLs arrived in Belfast on 9

[1] Also called T lymphocyte, type of leukocyte (white blood cell) that is an essential part of the immune system
[2] A life-threatening disease of severe hyperinflammation caused by uncontrolled proliferation of activated
[3] A cancer of the immune system that develops from abnormal lymphocytes
[4] One of the nine known human herpesvirus types in the herpes family, and is one of the most common viruses in humans.
[5] Concentrated antibody preparations that provide immediate short-term protection against disease for individuals at high risk of severe disease or serious complications from the disease.
[6] T-cells, derived from healthy donors that have been primed to recognise and destroy cells infected with EBV
[7] medicinal products that are not authorised for marketing in the UK

June 2021. Unfortunately, the patient's condition deteriorated acutely on the evening of 9 June 2021 and she sadly passed away the following morning before the Trust had the opportunity to administer the EBV-CTLs.

Issue(s) of complaint

5. The issue of complaint accepted for investigation was:

Whether the Trust sourced and facilitated the transport of EBV-CTLs in a reasonable, appropriate and timely manner?

INVESTIGATION METHODOLOGY

6. In order to investigate this complaint, the Investigating Officer obtained from the Trust all relevant documentation together with its comments on the issues raised by the complainant. This documentation included information relating to the Trust's handling the complaint.

Relevant Standards and Guidance

7. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those which are specific to the circumstances of the case. I also refer to relevant regulatory, professional and statutory guidance.

The general standards are the Ombudsman's Principles[8]:

- The Principles of Good Administration

8. The specific standards and guidance referred to are those which applied at the time the events occurred. These governed the exercise of the administrative functions and professional judgement of those individuals whose actions are the subject of this complaint.

The specific standards and guidance relevant to this complaint are:

[8] These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

- Belfast Health and Social Care Trust (BHSCT) Adjudication of New Medicines (and Treatments), October 2018 (Trust Adjudication of New Medicines)
- Belfast Health and Social Care Trust (BHSCT) Regional Unlicensed Medicines Policy April 2019 (Unlicensed Medicines Policy);
- Belfast Health and Social Care Trust (BHSCT) Medicines Code Policy, February 2020 (Trust Medicines Code Policy)
- Belfast Health and Social Care Trust (BHSCT) SOP PQS1.4 Change Control November 2018 (Trust SOP Change Control); and
- Belfast Health and Social Care Trust (BHSCT)Pharmacy and Medicines Management Central Procurement SOP CP22 undated (Trust Pharmacy Supplier Qualification Checklist);

Relevant sections of the guidance considered are enclosed at Appendix three to this report.

9. In investigating a complaint of maladministration, my role is concerned primarily with an examination of the administrative actions of the body complained of. It is not my role to question the merits of a discretionary decision taken unless that decision was attended by maladministration.

10. I did not include all of the information obtained in the course of the investigation in this report but I am satisfied that everything that I consider to be relevant and important was taken into account in reaching my findings.

11. A draft copy of this report was shared with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations. The Trust did not have any comments to make in response to the draft report. The complainant raised a number of issues. I have addressed those issues where possible in the body of the report.

THE INVESTIGATION

Whether the Trust sourced and facilitated the transport of EBV-CTLs in a reasonable, appropriate and timely manner?

Detail of Complaint

12. The complainant said that there was a '*significant and substantial delay*' between the Trust's decision to treat the patient using EBV CTLs on 26 May 2021 and the cells' arrival in Belfast on 9 June 2021. The Trust did not send a purchase order for the cells to SNBTS until 3 June. The Trust did not give the purchase order a priority rating. The complainant highlighted the '*critical*' period between 3 June and 7 June when he said there appeared to be '*nothing happening*', other than the courier working on a transport route.

13. The complainant said it was hard to understand why it took two weeks to transport urgently required medicine '*from one part of the UK to another*'. He offered to personally facilitate transport of the cells to Belfast given the urgent need to begin treatment, but the Trust refused his offer. He believed the delay occurred because the Trust did not have '*reasonable, adequate and appropriate tissue access procedures in place*'.

Evidence Considered

Legislation/Policies/Guidance

14. I considered the following guidance:
    - Trust Adjudication of New Medicines;
    - Unlicensed Medicines Policy

Relevant extracts are enclosed at Appendix three to this report

The Trust's response to investigation enquiries

15. The Trust provided a timeline which it stated accounted for its actions '*to safely procure*' the EBV CTLs following its decision to use them to treat the patient. The purchase order it sent to SNBTS on 3 June '*was only a formality*' as it had previously communicated the '*urgency of the order*' to SNBTS. It explained,

'*that there were a number of actions taken between Thursday 03 June 2021 and Monday 07 June 2021*', the details of which it summarised in the timeline.

16. In response to the complainant's belief that the Trust did not have reasonable, adequate and appropriate tissue access procedures in place, it explained that EBV CTLs were classified as a pharmaceutical product and as such '*tissue access procedures were not relevant*' to the process of obtaining the cells.

17. The Trust had not requested EBV CTLs before. The '*procurement, receipt, issue and dispensing*' of the cells was new to the service. Therefore, it took all necessary action '*to safely procure the product with expediency*'.

The Trust's records

18. I considered the Trust's records.

19. The Trust's records document that following blood tests on the patient, SNBTS confirmed on 28 May it had EBV CTLs which were a suitable match for the patient. The Trust had not previously procured, shipped, or stored the product before. The cells were classified as an unlicensed medicine. Between 28 May and 1 June, the Trust carried out a number of actions in relation to obtaining the EBV CTLs. These included making enquiries to determine the nature of the product, finding suitable storage facilities, confirming supply and logistics details and carrying out risk assessments. Trust staff identified that a freezer in Victoria Pharmaceuticals on the Royal Victoria Hospital site was the only suitable location for storing the EBV CTLs. The third party who owned the freezer gave the Trust permission to store the EBV CTLs in it on 2 June.

20. On 2 June the Trust approved an '*urgent drug application for a single patient*'. This is a form the Trust uses in time critical cases. This form supersedes the regional Unlicensed Medicine Proposal form normally used when requesting a new unlicensed medicine. The Form is an appendix of the Trust Adjudication of New Medicines.

21. An internal email documents that on 2 June the pharmacy team member responsible for the procurement of the EBV CTLs had already received

confirmation from SNBTS on how it would ship the cells. The staff member noted '*I just emphasised the urgency-safe but urgent*'. On 3 June the Trust sent a purchase order to SNBTS to obtain the cells.

22. On 4 June the Trust contacted SNBTS to ask for a progress update and indicated that it would pay out of hours costs to ensure that the third-party courier dispatched the cells within the next 24 hours.

23. On 7 June the Trust sent a letter to the third-party courier stressing the urgency of its request and to ask the courier to expedite delivery of the cells at the earliest possible opportunity.

Interview with Trust staff

24. The investigating officer spoke to a Trust staff member involved in the procurement of the EBV CTLs. He explained the following points: it was SNBTS' responsibility to ensure the safe preparation and transport of cells. SNBTS used a validated third-party courier with significant experience of transporting frozen cells to deliver products on its behalf. The courier would need a licence from the Medicines and Healthcare products Regulatory Agency[9] (MHRA) to distribute unlicensed medicines. Given the time constraints involved in sourcing and validating another courier, the most appropriate course of action was to use SNBTS' courier. Any time the Trust spent sourcing and validating a courier would have impacted on the work to prepare for the cells' arrival in Belfast.

Enquiries with SNBTS staff

25. The investigating officer spoke to the SNBTS staff member who liaised with the Trust pharmacy team to supply the EBV CTLs and arrange their transport to Belfast. The staff member explained the following: the complainant would not have able to facilitate transport of the cells himself. As the manufacturer SNBTS '*must do it*' in accordance with Good Distribution Practice[10]. The

[9] An executive agency of the Department of Health and Social Care in the UK which is responsible for ensuring that medicines and medical devices work and are acceptably safe
[10] An EU and UK regulation which requires that medicines are obtained from the licensed supply chain

transport of the cells came under '*the terms of* [its] *licence*'. It was obliged to ensure the cells were '*going to the right place and correct conditions'* and that suitably trained personnel carried out this action. It contracted out the distribution work to a third-party courier who fulfilled these requirements.

26. It provided four weeks' supply of EBV CTLS in each shipment. Once the dry shipper[11] is opened the cells begin to defrost. The cells need to be used once they have thawed and cannot be refrozen. To ensure this does not happen and the entire shipment remains effective the cells are transferred to a suitable freezer immediately upon receipt.

27. The reduction in available flights in 2021 due to travel restrictions during the pandemic contributed to delays in shipping the cells.

Analysis and Findings

28. The complainant said he found it '*inconceivable*' the Trust took over two weeks to ship the EBV CTLs from Edinburgh to Belfast. He offered to personally facilitate transport of the cells to Belfast, but the Trust refused his offer. SNBTS stated that due to regulatory requirements it would have been unable to allow the complainant to organise transport of the cells to Belfast. Therefore, while I acknowledge the complainant's frustration at the Trust's refusal to accept his offer, ultimately it would not have been possible for him to facilitate transport of the cells himself.

29. In order to determine if the Trust's efforts to obtain the EBV CTLs were reasonable and appropriate, I examined its actions prior to sending the purchase order to SNBTS on 3 June. I then examined its actions between 3 to 7 June to consider if it facilitated the transport of the cells in a reasonable manner.

28 May to 3 June

30. The patient's medical records document that her consultant haematologist

and are consistently stored, transported and handled under suitable conditions.

[11] also known as cryogenic shipping, or liquid cylinder transport, dry shippers are the coldest shipping solution available and maintain a temperature between -150°C and -196°C

decided to use EBV CTLs to treat her on 26 May. I note that SNBTS, the licensed supplier of the cells confirmed on 28 May it had a suitable match for the patient. The patient's consultant contacted the Trust's pharmacy department on 28 May to request the treatment.

31. Following enquiries with SNBTS on 28 May, the pharmacy team confirmed the cells were an unlicensed medicine. I refer to the Trust's Unlicensed Medicines Policy which requires pharmacy staff to '*ensure correct storage arrangements*' for any unlicensed medicine. I note pharmacy staff contacted SNBTS to establish the conditions under which the cells needed to be stored and immediately began to investigate the possible storage options within the Trust.

32. I examined email correspondence between staff involved in procuring the EBV CTLs. The correspondence documents that the Trust had not used EBV CTLs before and the pharmacy team had no experience in receipt, handling or storage of EBV CTLS. I refer to the Unlicensed Medicines Policy, which states that '*New unlicensed medicines should only be introduced following appropriate risk assessment and product categorisation*'. I note pharmacy staff liaised again with SNBTS on 31 May to obtain further details on the product and to identify any possible risks. Following receipt of the additional information, the Trust carried out an initial risk assessment on 1 June.

33. On 30 May, pharmacy staff established there was only one freezer within the Trust suitable for storing the cells. A third party owned the freezer and the Trust sought and obtained formal permission to use it on 1 June following the mandatory risk assessment by pharmacy staff referred to above. In his response to the draft report the complainant asked why the Trust could not buy a suitable freezer. The Trust stated it had put a Service Level Agreement in place with the freezer's owner to ensure it could use it to store any future consignments of stem cells. It stated that as it needed to store stem cells so infrequently this was the most expedient arrangement.

34. The complainant was concerned the Trust did not send a purchase order to SNBTS until 3 June and additionally it did not give the order a priority rating. I considered the Trust's response that the purchase order was '*only a formality*'

and it had already communicated the urgency of the order to the supplier. I examined the Trust's records which show that the pharmacy department approved the request for EBV CTLs from the patient's consultant on 2 June and sent the purchase order to SNBTS the following day. However, I also examined correspondence between SNBTS and the courier company it used to transport cells and I note that on 1 June SNBTS approached its courier for a quote for transportation of the EBV CTLs to Belfast. Internal emails also document the Trust and SNBTS had agreed the method of shipping the cells by 2 June. I am therefore satisfied the Trust's response was correct and it had already initiated the process of ordering the cells by 1 June, albeit in an informal capacity.

35. In his response to the draft report the complainant said he believed the issue of the freezer was a '*red herring*' used to justify delay '*after the fact*'. I note SNBTS' explanation that the cells would begin to defrost once the Trust opened the shipper they were transported in, and they could not be refrozen. It was therefore necessary for the Trust to ensure that it transferred the cells to a suitable freezer upon receipt to ensure their effectiveness. Having examined the records documenting the efforts of pharmacy staff to secure the use of the freezer, carry out risk assessments and put the conditions in place to facilitate the storage of the cells, I am satisfied that the actions of the Trust in relation to this issue were necessary and appropriate.

36. In summary, I examined the Trust's actions between 28 May and 3 June. The patient's consultant made an urgent request to the pharmacy department on 28 May for EBV CTLs. The product was a new unlicensed medicine which required pharmacy staff to follow a number of procedures, including categorising the product, risk assessment, receipt, storage suitability and confirming supplier qualifications. While the records document that the Trust did not send a purchase order to SNBTS until 3 June, it is evident the actual process of obtaining the cells began as early as 1 June. I consider the correspondence between staff involved in the procurement process reflects a recognition of the urgency of the situation, balanced with a need to ensure the team followed mandatory procedures.

3 June to 7 June

37. The complainant said he found it difficult to understand how it took so long to transport potentially lifesaving medicine between Edinburgh and Belfast. He believed that there was '*nothing happening*' between 3 June and 7 June. I acknowledge the complainant's concern. There was no indication in the Trust's response to the complainant of any progress or action taken during this period.

38. I note that following the Trust's request for EBV CTLs, SNBTS contracted its regular third-party courier to transport the cells from Edinburgh to Belfast. The Trust explained that using the third-party courier was the most appropriate course of action as the courier was a licensed logistics company with significant experience in transporting frozen medical products. The Trust stated that given the urgency of the situation it would not have been appropriate for it to begin to source another logistics provider. It also explained that any time spent sourcing and validating another courier could have impacted on its preparations to receive the cells. I consider that the Trust's explanation is reasonable.

39. I examined the Trust's records which document that on 3 June the Trust received notification the courier would begin transport of the cells on 7 or 8 June. On 4 June the Trust contacted SNBTS to ask for an update. It also indicated that it was willing to pay out of hours costs to ensure the courier shipped the cells within the next 24 hours. On 7 June SBNTS contacted the Trust to advise that the courier had not collected the cells for transport and that it anticipated a shipping date of 10 June. In response the Trust met virtually with SNBTS and the courier to resolve the situation. I note that following the meeting it sent a formal request to ask the courier to explore all possible transport routes and to safely expedite the journey to Belfast. Following the Trust's intervention, the Courier shipped the cells on 8 June and they arrived in Belfast on 9 June.

40. In summary, the Trust stated it used the supplier's third-party courier to transport the cells because of its experience in transporting frozen medical products that could not be x-rayed. I further note SNBTS' explanation that as

the manufacturer it was ultimately responsible for organising transport of the cells in accordance with the regulatory requirements and as such it used a courier that allowed it to meet those obligations. In light of this, I consider it was reasonable for the Trust to use the supplier's courier given that the patient urgently required the cells and that the Trust had no previous experience in procuring or transporting them. I also consider that the Trust took steps to convey the urgency of its request to the courier and sought to expedite the process where possible.

41. Overall, I am satisfied the Trust's actions to source the EBV CTLs were reasonable, appropriate and timely. The complainant believed the delay in obtaining the cells occurred because the Trust's tissue access procedures were not adequate. However, it is clear the EBV CTLs were an unlicensed medicine the Trust had not used before. As such I consider the Trust correctly followed the mandatory procedures in its Unlicensed Medicines Policy and that there was no 'blanket policy' it could apply to obtain the cells immediately. In addition, there is clear evidence the Trust took active steps to begin the procurement process once the consultant made the request for the cells. In relation to the transport of the cells, I consider the Trust's decision to use the supplier's courier was reasonable, given the courier's knowledge and experience of the process and SNBTS' explanation that it was ultimately responsible for facilitating transport. It is also clear the Trust took active steps to expedite the process. Therefore, I do not uphold this issue of complaint.

42. In response to the complainant's concerns regarding the period of time it took to acquire the cells, the Trust stated that it had provided training to pharmacy to address '*the logistical, technical and clinical challenges'* of acquiring the cells.

43. The complainant said that his wish was to ensure that patients who required stem cell treatment at a future date did not experience the delays that the patient did when she was awaiting treatment. He highlighted the disparity between patients in Great Britain where stem cells could be quickly and easily transported by road from the distribution centre, to those patients in Northern Ireland, where Trusts were required to transport the cells via air freight. I

acknowledge the complainant's concern. However, I consider that these are issues largely beyond the Trust's control. I note the Trust has made efforts to streamline its internal control procedures to help minimise delay. I share the complainant's hope that this will benefit patients requiring stem cell treatment in the future. I commend the Trust for its actions.

CONCLUSION

44. I received a complaint about the actions of the Trust. The complainant raised concerns about the length of time it took to procure EBV CTLs to treat his wife's condition.

45. The investigation found that the Trust's actions to procure and transport the EBV CTLS were reasonable and appropriate. The product was an unlicensed medicine that the Trust had not sourced, transported or stored before.

46. I am in no doubt that the patient's deterioration and her tragic death on 10 June must have been highly distressing and traumatic for the complainant, particularly as the potential lifesaving treatment sourced by the Trust did not arrive until it was too late for the patient. However, my investigation found no evidence of failing on the part of the Trust in relation to any of the concerns the complainant raised about the Trust's actions to procure and transport the cells.

47. Given the findings of my investigation, I do not uphold the complainant's complaint about the Trust's actions to procure the cells between 28 May and 9 June 2021. In his response to the draft report the complainant expressed his strong disagreement with elements of the report's findings. In conversation with the investigating officer, he expressed the view that '*there was always a way to get things done*'. I understand and acknowledge the complainant's view and I sincerely regret the Trust's efforts to procure the cells did not change the patient's outcome. I extend my deepest sympathies to the complainant for the loss of his wife.

Margaret Kelly
Ombudsman **February 2024**

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

- Acting in accordance with the law and with regard for the rights of those concerned.
- Acting in accordance with the public body's policy and guidance (published or internal).
- Taking proper account of established good practice.
- Providing effective services, using appropriately trained and competent staff.
- Taking reasonable decisions, based on all relevant considerations.

2. Being customer focused

- Ensuring people can access services easily.
- Informing customers what they can expect and what the public body expects of them.
- Keeping to its commitments, including any published service standards.
- Dealing with people helpfully, promptly and sensitively, bearing in mind their individual circumstances
- Responding to customers' needs flexibly, including, where appropriate, co-ordinating a response with other service providers.

3. Being open and accountable

- Being open and clear about policies and procedures and ensuring that information, and any advice provided, is clear, accurate and complete.
- Stating its criteria for decision making and giving reasons for decisions
- Handling information properly and appropriately.
- Keeping proper and appropriate records.
- Taking responsibility for its actions.

4. Acting fairly and proportionately

- Treating people impartially, with respect and courtesy.
- Treating people without unlawful discrimination or prejudice, and ensuring no conflict of interests.
- Dealing with people and issues objectively and consistently.
- Ensuring that decisions and actions are proportionate, appropriate and fair.

5. Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Putting mistakes right quickly and effectively.
- Providing clear and timely information on how and when to appeal or complain.
- Operating an effective complaints procedure, which includes offering a fair and appropriate remedy when a complaint is upheld.

6. Seeking continuous improvement

- Reviewing policies and procedures regularly to ensure they are effective.
- Asking for feedback and using it to improve services and performance.
- Ensuring that the public body learns lessons from complaints and uses these to improve services and performance.