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The investigation of a complaint against Aneurin Bevan University Health Board

A report by the
Public Services Ombudsman for Wales
Case: 202301069

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Introduction

This report is issued under s.23 of the Public Services Ombudsman (Wales) Act 2019.

In accordance with the provisions of the Act, the report has been anonymised so that, as far as possible, any details which might cause individuals to be identified have been amended or omitted. The report therefore refers to the complainant as Mrs X.

Summary

Mrs X complained that Aneurin Bevan University Health Board ("the Health Board") failed to offer her treatment with the drug fampridine after its approval for NHS use in Wales in December 2019. Fampridine may help certain patients who have multiple sclerosis.

I **upheld** the complaint.

My investigation found that, despite fampridine being approved for NHS-funded use in Wales in 2019, the Health Board had still not put in place arrangements to offer fampridine to any eligible patients within its area. This included Mrs X. In my view, this amounted to maladministration which resulted in ongoing injustice to Mrs X. She remains unclear as to when or if she will have access to this potentially life improving medication.

I recommended that the Health Board should apologise to Mrs X, and put in place an action plan, with timescales and board oversight, to ensure that the introduction of fampridine was implemented in a timely manner.

The Complaint

1. Mrs X complained that Aneurin Bevan University Health Board ("the Health Board") failed to offer her treatment with the drug fampridine after its approval for NHS use in Wales in December 2019.

Investigation

2. My Investigation Officer obtained comments and relevant information from the Health Board and considered these in conjunction with the evidence provided by Mrs X. I have not included every detail investigated in this report, but I am satisfied that nothing of significance has been overlooked.

3. Both Mrs X and the Health Board were given the opportunity to see and comment on a draft of this report before the final version was issued.

The background events

4. Fampridine was approved by the Welsh Government as an NHS-funded treatment in Wales in December 2019 following a recommendation by the All Wales Medicines Steering Group (AWMSG).[1] Generally, newly approved medicines should be offered within 60 days of approval by the Welsh Government.

5. Fampridine was approved for NHS use to improve walking in adult patients with multiple sclerosis (MS - a degenerative condition affecting the central nervous system). Mobility and changes to a person's level of mobility over time are monitored and quantified using the Expanded Disability Status Scale ("EDSS"). Fampridine was approved for patients who had an EDSS score of between 4 (able to walk for 500 metres without an aid) and 7 (able to walk no more than 5 metres even with an aid).

6. Mrs X complained to the Health Board in February 2023, because she remained unable to access the drug despite its approval as an NHS-funded treatment in Wales in 2019.

[1] All Wales Medicines Strategy Group Advice No: 1919 – December 2019
Final Appraisal Recommendation (nhs.wales)

7. In its formal response letter to Mrs X, dated 3 May 2023, the Health Board acknowledged that it had been unable to offer the drug. It stated that fampridine can only be prescribed by a doctor experienced in the management of MS. A walking assessment was needed before starting the drug, and then follow-up assessments by the MS MDT (multi-disciplinary team), spasmolytic therapy (to relieve muscle contractions) and physiotherapy. It estimated that there may be around 500 patients within its area who may be eligible to trial this treatment. It stated that it did not have the resources at present to offer this service as it would be unsafe to do so without having adequate staffing in place for effectively monitoring patients. It confirmed that a business case was being developed and once approved, the Health Board would have the resources to safely support the rollout of the drug to eligible patients.

Mrs X's evidence

8. Mrs X said that she fell into the category of a patient with MS who had an EDSS of between 4 and 7. Therefore, she could potentially benefit from the drug and was within the category of patients who would be eligible to receive it. She was disappointed to not be offered the drug by the Health Board, when she was aware that it had been approved and that other health boards were offering it.

The Health Board's evidence

9. The Health Board accepted that the current situation was very disappointing for its patients. It stated that it was keen for the service to be set up. However, it needed additional resources for the staff required to properly monitor the prescribing and use of the drug for eligible patients. It explained that it had started preparing a business case for the introduction of fampridine in November 2022, and this had been completed and submitted to the Health Board's own Pre-Investment Panel in September 2023 for approval for funding. It confirmed that an amended version would be re-submitted to the Panel in January 2024 for approval. Once funding was approved, the Health Board could begin the process of recruitment of suitable staff to ensure the safe roll-out of fampridine treatment. It expected the recruitment to take between 3 to 6 months to complete.

10. The Health Board confirmed that it was not able to refer patients to other health boards nearby, as the 2 largest ones already had waiting lists for accessing fampridine within their own areas. Fampridine is not NHS-funded in England, so the Health Board stated there was no possibility of seeking an agreement to refer patients there for treatment.

Analysis and conclusions

11. It is evident, from the information I have seen, that the Health Board has failed to offer fampridine to eligible patients in line with its approval for NHS use in Wales. It was approved for use in December 2019. Taking into account the 60-day limit for provision of newly approved medication, the Health Board should have been in a position to offer it to patients by March 2020.

12. I accept that additional staffing resources are required in order to properly assess and monitor patients when fampridine is administered. I also note that the initial period of implementation coincided with the COVID-19 pandemic with the resulting significant strain on healthcare resources and staff. It is therefore understandable that the Health Board was not able to implement the assessment framework for the introduction of fampridine at this point. My office is aware that other health boards similarly encountered delays in introducing fampridine during this period but have done so since. It is concerning that the drug remains unavailable to patients within the Health Board's area, and it is still not able to confirm when this will change.

13. I accept that the Health Board has stated that this is a resource issue. It is for the Health Board to decide how it distributes its resources in delivering its services. However, the approval of a drug for NHS use by the Welsh Government creates a legitimate expectation amongst the public that this will be made available to those eligible to receive it within a reasonable period of time. As matters stand, 4 years from the date of approval for NHS-funded use in Wales, the Health Board has not made fampridine available to any patients within its area. It is also unable to give a date as to when it may be able to do so. Given this situation, I can

completely understand the frustration that Mrs X feels that an NHS-funded treatment that may benefit her, remains unavailable to her because the Health Board in the area where she lives does not provide it.

14. There are many occasions when patients are placed on a waiting list for treatment due to the pressures of resources and the demand for a particular drug or procedure. However, I am satisfied that the provision of fampridine by the Health Board is a wholly different issue. It is not offering the drug to any of the eligible patients within its area. In my view, the Health Board appears to have taken minimal steps to implement the service which has resulted in an unacceptable delay in providing the drug. The date of approval for fampridine for NHS Wales funded provision was December 2019. The Health Board started formulating its business case for the service to provide this treatment in November 2022, and funding for this service has yet to be approved. Even if it is approved immediately, the Health Board has estimated another 3 to 6 months to recruit staff. This means that the earliest fampridine could be offered to patients is the middle of 2024. This represents over 4 years since the approval of fampridine as an NHS-funded treatment in Wales.

15. I am satisfied that the Health Board has failed to put in place reasonable and timely arrangements in order to start offering fampridine to patients within its area. This amounts to maladministration which has caused and continues to cause injustice to Mrs X who remains unclear as to when or if she will have access to this potentially life improving medication. I therefore **uphold** this complaint.

Recommendations

16. I **recommend** that the Health Board, within **1 month** of the date of this report, should:

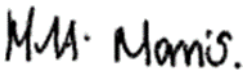
a) Provide a formal written apology to Mrs X for the shortcomings identified in this report.

b) Establish an action plan, with timescales, to expedite the provision of fampridine by the Health Board.

c) Share this report with the Board or relevant committee who should oversee and regularly review the action plan to ensure that timely progress is made and that the actions are fully completed.

I also intend to write to the Welsh Government to bring the findings identified in this report to its attention.

17. I am pleased to note that, in commenting on the draft version of this report, the Health Board has agreed to implement the above recommendations.



1 February 2024

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