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Mr William Powell AM
Chairman
Petition Committee
National Assembly for Wales
CARDIFF
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13/8/15

Dear Mr Powell,

Re: Petition P-04-571 Treating Pernicious Anaemia

Thank you for your correspondence of the 5th August regarding the above petition.

I offer the following observations on the points made by the Minister for Health and Social Services in his letter to you of the 21st May.

This society acknowledges that the new Guidelines on Cobalamin and Folate produced by the British Committee for Standards in Haematology is a thorough and in-depth analysis of the problems with the diagnosis of B₁₂ Deficiency and whether that deficiency is due to Pernicious Anaemia. The guidelines acknowledge that the current test to determine B₁₂ status in patients is flawed and that physicians should ignore the test results and treat the patient if he or she shows the symptoms of the deficiency. An alternative test – the ‘Active B₁₂ Test’ shows the promise for it to be a more reliable assay but is still being evaluated by clinicians some of whom are critical of it. Similarly the new Guidelines recognise that test used to determine whether the patient’s B₁₂ deficiency is due to Pernicious Anaemia (the inability to absorb B₁₂ from food due to intrinsic factor antibodies) is similarly flawed and testing negative for the antibodies means that the patient could have negative antibodies Pernicious Anaemia which, frankly, means that whatever the outcome of the test the patient should receive a diagnosis of having Pernicious Anaemia.

This society has been made aware of a new, more accurate assay that has been developed in Australia that addresses these problems by using other indicators of B₁₂ Deficiency other than the amount in the patient's blood. However, although this new test has shown exceptional promise in development trials it is still many years before it will be available. In my next book that is published in October I have consulted several experts on B₁₂ from many different parts of the world. B₁₂ Deficiency is a serious worldwide problem and if my calculations are correct around 300,000 people in Wales will have a B₁₂ Deficiency and, because we are a developed country, the biggest cause of that deficiency will be Pernicious Anaemia – and there is no accurate test available to allow doctors to produce a correct diagnosis. It is a serious problem that is, thankfully now being addressed.

The above is just background material mentioned by the Minister and I now turn to the second problem faced by this society's members – receiving adequate treatment for their condition and this forms the subject matter of this petition. Patients with Pernicious Anaemia will be unable to absorb vitamin B₁₂ from food. In the past this led to patients dying a slow death but, from the mid 1920's it was discovered that giving patients copious amounts of preferably raw liver or other offal meant that they could be kept alive. Liver extract injections were made available in the late 1940s and by 1960 'artificially produced B₁₂' was made available which is injected and means patients should lead a more or less normal life. Unfortunately the injections that were given monthly in the 1960's was changed to every two months in 1974 and then to every three months in 1984. By far the biggest cause of complaint by this charity's members relates to their treatment. Whilst some of our members manage perfectly well on a three monthly replacement therapy injections others don't and feel a return of their symptoms sometimes well before their next injection is due. Nobody knows why this is so but I can report that we are about to embark on a small feasibility study led by Professor John Hunter to test his theory of why some patients need more frequent injections.

The new Guidelines as mentioned earlier are disappointing in relation to the treatment of Pernicious Anaemia in that they state quite early on that the question of treatment is a matter for the British National Formulary (BNF). I met with the Director of the BNF late last year and was told that if I was able to produce evidence that some doctors prescribe more frequent injections than one every three months that they might 'change the wording' of the instructions for treating Pernicious Anaemia. I am currently working on this.

Like the new guidelines NICE's Clinical Knowledge Summary of the management of Pernicious Anaemia is unhelpful in this respect stating:

'Some experts acknowledge that there is a small group of patients who report a recurrence of their symptoms earlier than 3 monthly.

CKS could find no guidelines or evidence on the management of this group.

Feedback from expert reviewers differs with regard to whether or not more frequent intramuscular injections of hydroxocobalamin 1 mg are required, and if they are, what regimen to suggest'.

Sadly no research has been conducted to explore and investigate this other than the programme we are about to embark on. In the meantime many of our members who are

unable to receive more frequent injections based on their individual needs are forced to pay for more injections from various sources: doctors, beauticians, hair dressers, the internet or from pharmacies in continental Europe where they are available 'over the counter'. What makes our members angry is the number of 'celebrities' who receive regular B₁₂ injections (mostly weekly) to help them with their energy levels and creativity while we, as patients, need the injections to stay alive. A recent survey of over 1,000 of our members published in the British Journal of Nursing in 2014 showed that:

'When asked if they were satisfied with their treatment, 64% said 'No', 28% said 'Yes' and the remaining 8% did not provide an answer'.

It's worth noting that of those 28% who answered yes some will be self-treating. Indeed 10% of those surveyed were self-treating with a form of B₁₂ that isn't licensed in the UK.

In a recent written answer to questions made in the House of Lords the Dept. of Health stated that the treatment patients' receive should be a matter decided by the patient and their doctor. This is what Lord Prior of Brampton stated:

'When anaemia is diagnosed, most patients respond well to treatment through quarterly intramuscular injection of vitamin B12. Whilst some patients with Pernicious Anaemia might prefer to have more frequent injections, or for other forms of vitamin B12 to be self-administered, these are matters for individual patients to discuss with their general practitioners'.

Unfortunately whilst some doctors are willing to depart from the guidance in the BNF most are not. This means that many of our members who cannot afford the often ridiculously high costs of injections given outside the NHS (one Harley Street clinic charges £148 for a 38p injection) are left to suffer a return of their symptoms often for many months before they feel well again. It is worth noting that often it is the patient's family, friends and work colleagues who notice the patient's deterioration in the run up to his or her next injection.

I note that the Minister's letter to you mentions that the Dept. of Health's Medicines Pharmacy and Industry Group are encouraging pharmaceutical companies to introduce 'new formulations' available. Such formulations already exist and are used by our members – nasal sprays, sub-lingual sprays, sub-lingual drops, skin patches etc. but none of these has been evaluated as to their efficacy and none have been licensed in the UK. There is only one other licensed product for treating B₁₂ Deficiency in the UK – oral tablets. There is always the option for our members to buy very high dose B₁₂ tablets from Amazon. The NHS currently does not provide the very high-dose tablets needed to hopefully treat any deficiency caused by Pernicious Anaemia – (remember, we cannot absorb B₁₂ in our stomachs but high dose tablets *might* work) but it is worth taking note of what the new guidelines have to say about oral treatment:

'However, the efficacy and cost-effectiveness of oral treatment in wider population-based settings has yet to be established. There are arguments against the use of oral cobalamin in initiation of cobalamin therapy in severely deficient individuals who have poor absorption, especially due to Pernicious Anaemia'.

I met with Prof David Haslam, Chairman of NICE last year and he is fully aware of the problems faced by our members. I support his suggestion that this issue be referred to the Dept. of Health on an 'exceptional basis'.

I apologise for the length of this letter but I want you to be fully aware of what is happening to many of our members. There is a problem with a great many patients receiving adequate patient-centred treatment and that includes our members living in Wales. This lack of flexibility in treatment is causing serious problems in the domestic situation, in the workplace, in education and in social settings. Whilst there is acknowledgement that the way in which B₁₂ Deficiency and Pernicious Anaemia is diagnosed is, as one Professor of General Practice described it "a mess" there are also serious problems with the way in which Pernicious Anaemia is treated for a great many though not all of our members.

I do hope this helps. Should you require any further information please don't hesitate to contact me in order that I can be of help.

Thank you and your colleagues for taking an interest in this issue.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Martyn Hooper', with a stylized flourish at the end.

Martyn Hooper
Chairman