

Members of the committee,

Firstly I would like to thank you for taking the time to consider the points of our petition. I feel this petition is made as free of political partisanship as is possible. However I feel a duty of care has to be shown by any government that is in office.

Whilst I know that your remit may be limited you do have an ability to move some of our concerns on for further discussion. I hope you will find enough here to do so.

For the sake of these notes I am using my wife's case as an example of the pitfalls and difficulties that are experienced by many very ill and vulnerable patients throughout Wales.

I am confining additional points to the headings of "Additional Notes" taken from our petition.

An important point I wish to make to you is that in the case of my wife, as with many other people, the real danger of death is ever present. We know that change of some sort is overdue and extremely urgent.

Brief synopsis of the case of Kate (Example Case).

Kate is 33 years old and was diagnosed with Acromegaly in December 2009.

Treatment to date which consisted of ten hours of brain surgery, 26 radiotherapy sessions and the administering of the drug Octriotide have so far failed to improve her condition. As a result it continues to decline. She is a patient strongly thought to be in a position to substantially benefit from a drug called Pevisomant. A request and subsequent appeal to the WHSSC for this drug have both been unsuccessful even in the face of recent and positive clinical data. This is not an isolated case and drugs and treatments are regularly being declined to patients causing untold damage. We don't for one moment say that every drug and treatment should be handed out but the decision process is extremely flawed and needs to be transparent, fair and above all the right thing to do.

Points for your consideration.

1. When the WHSSC assess a requested drug the recommendations from the All Wales Medicines Strategy Group (AWMSG) should be no more than 18 months old. This is due to the fact those that are years old do not have a reliable bench mark. Reliable data for all medicines improve day by day as case studies multiply. The WHSSC should have the right to request an up to date review from the AWMSG and this should be carried out as a matter of urgency.

This of course might be impractical due to the amount of drugs listed but as in the example case it should be possible for the AWMSG to be approached on a particular drug by clinicians or the WHSSC to reassess a drug as a matter of urgency. In the case of Kate the bench mark used is from 2005. The WHSSC themselves pointed out that an urgent review of this drug should be carried out by the AWMSG.

NICE (National Institute for Clinical Excellence) recommended back in 2009 that Pegvisomant was a drug they felt did not need a full recommendation from them. They felt it was appropriate that this drug should be used and decided on a case by case basis by individual Primary Care Trusts.

NICE guidelines for unlisted medications is as follows....

“Medicines and treatments not recommended or assessed by NICE

The NHS is not legally obliged to fund a medicine or treatment not recommended by NICE, even if your GP thinks it would benefit you.

In fact, most NHS medicines and treatments have never been looked at by NICE. The Department of Health (DH) only asks NICE to provide guidance when there’s uncertainty over the use of a treatment.

All medicines must be licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). There is no ban on prescribing licensed medicines that NICE has not yet assessed or where a NICE appraisal is in progress.

The DH has issued clear guidance to local organisations, such as Primary Care Trusts (PCTs) and NHS Trusts, on what to do when NICE has not issued guidance on a new medicine. In these circumstances, the DH expects PCTs to take into account all the evidence available when deciding whether to fund treatments. “

(Here you see that the DH expects the latest available information to be considered. In this case as with many others this has not been done)

2. When the WHSSC declines a request for a medicine an appeals process is then initiated in which the patient, doctors or an advocate can be present but none are allowed to speak.

This must not continue therefore the WHSSC should by law be required to hear the case with the full participation of the patient, doctors or advocate.

This does not need to be elaborated on too much. It has to be obvious that an appeal should be a forum for all vested opinions to have a say. At present this is how appeals work. The question is who does this help. Quite easily this can be changed by giving a voice to those best able to put a case forward. Having an appeal that you can't appeal at is a nonsense by any standard.

3. In many cases patients are extremely ill, alone and vulnerable. It should be a priority to make sure such patients have an advocate to help them through the procedures in place for the funding of medicines. Doctors have large case loads so are unable to give extra time to patients.

The Minister of Health herself believes patients have their doctors as advocates. This is not true nor practical.. There are organisations that may be able to assist (without cost or very little) patients who find themselves alone, confused and frightened. It should be a relatively practical to make support in the process of applying for drugs available to patients who need it.

4. A review of the actual costs of specialized medicines that have been refused and the subsequent hospital admissions, alternative treatment costs should be carried out. This would be beneficial to determine the true costs of specialized medicines to the tax payers.

In many cases not giving requested treatments can result in far higher costs due to hospitalisation or heavier burdens on community or family carers. As complicated as this kind of information is to collect, analyse and review it should be looked at in the future to unearth the real costs.

5. The WHSSC should have the power to grant a medicine if the medical teams have concluded that all other treatments have failed and that the said medicine in their opinion has a chance to benefit the patient.

In the example case the only three possible treatments tried have been unsuccessful. The drug requested is the only alternative that has a chance to give real and positive results. Even if a drug proves unsuccessful it must be right to give Doctors and patients a window of opportunity to try it. The WHSSC if they already don't have the right to do so should be able to override AWMSG guides and fund a drug. The AWMSG should not become just another government rationing body.

6. The WHSSC should be given the option to at least give a patient a trial run with a drug to ascertain if a positive result could be expected.

This point makes sense as many drug companies will on occasion give a starting dose for free and possibly work on costs.

Conclusion:

Our points may come across as naive and difficult to pursue but what is at stake are peoples lives, wellbeing and hope. It is no exaggeration to point out that the system as it stands is not fair to patients and their families nor indeed to the tax payers of Wales.

I hope you will see that this attempt to bring this to the attention of the parliament has merit and deserves more than a pat on the head. In looking after my wife I am frustrated to be spending a vast amount of time trying to fight these issues. My wife and I are both of the opinion that others should not have to go through this ordeal. Your input and advice will be of great value to us. The outcomes of your discussions are very important to highlight this problem. I have no choice in the case of a negative response to but carry on.

The simple answer is that any drug that is licensed in the United Kingdom should, if clinically viable in the opinion of a team of specialists, be funded especially if no alternative exists. Sometimes life has to override economics.

Again I thank you for your time and consideration.

Jeremy Derl-Davis

24-02-2013