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Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref LF/MD/0055/15

Mr David Rees AM
Chair
Health and Social Care Committee
National Assembly for Wales
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Dear David,

21 January 2015

Thank you for your letter of 13 January 2015 regarding the Health and Social Care Committee's consideration of the Legislative Consent Memorandum (LCM), in relation to the UK Medical Innovation Bill, which requests clarification of discussions with the Department of Health over my concerns with this Bill.

My officials have had several discussions with colleagues in DH, and I wrote formally to Earl Howe setting out my concerns, on 13 November 2014, as well as providing some suggested amendments to the Bill to allay those concerns. The response I received to that letter from Earl Howe, whilst responding to the points raised, does not address my concerns and does not change my opinion that the provisions within the Bill should not apply to Wales.

Having taken further advice from the Deputy Chief Medical Officer I remain of the view that the Bill is not necessary, and is not consistent with the fundamental principles which we wish to drive improvements in NHS Wales.

In our view the Bill is unnecessary as there is no evidence that innovative care is prevented by doctors' fears of clinical negligence. An excellent recent example is the use of innovative treatments in the UK, Europe and Africa for the treatment of patients with Ebola. This experience has demonstrated clearly that innovation can take place within current arrangements.

It appears to us, therefore, that the existing common law rule to the effect that departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion works well, and there is no need for the alternative route allowing a doctor to undertake 'responsible innovation' set out in the Bill. We are concerned that the Bill will not make the position any clearer.

Clause 1 of the Bill provides it is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly. It also sets out a series of steps that a doctor must take for the purposes of taking a responsible decision, for example, obtaining the views of one or more appropriately qualified doctors in relation to the proposed treatment.

Amendments have been made to the Bill, at Committee and Report Stages in the House of Lords, to try to provide additional safeguards for patients. The view of the Welsh Government is that these amendments do not sufficiently improve the protection to patients and certainly do not make this Bill a positive influence for Welsh healthcare. Under the current law a doctor would not be negligent if they can show support for their decision from a responsible body of medical opinion. However, the test under the Bill is that in order to take a responsible decision to depart from the existing range the doctor must in particular obtain the views of one or more appropriately qualified doctors. We are concerned that innovating doctors may consider that it is only necessary to seek an opinion from one other doctor, even in circumstances where there is a wider responsible body of medical opinion which should be consulted.

The amendments also require the doctor to consider the views and best interests of the patient and to record their clinical decisions, but these are already legal requirements of all doctors, so the Bill does not add significantly to this.

We are, therefore, concerned that the Bill could have an effect which runs counter to the principles underpinning our policy in Wales for prudent healthcare. Prudent healthcare requires the consistent use of evidence based care in a way that minimises the possibility of avoidable harm. The Bill may encourage innovative treatments which do not necessarily fit with the Welsh Government's prudent healthcare policy. Many patients seeking the innovative treatments envisaged in this Bill will be seriously ill and potentially vulnerable. We would wish them to be treated compassionately with discussions around evidence based care. We believe the setting up of an alternative route for doctors to follow when proposing to innovate could lead to confusion around the types of treatment which should be offered to these patients, and may result in the use of experimental treatments which may be unsafe, and where there is no known likelihood of success.

For these reasons the Bill even with its amendments does not provide a positive influence for Welsh healthcare, and I remain of the view that the provisions within this Bill should not apply to Wales.

Best wishes,

Mark

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