

National Assembly for Wales / Cynulliad Cenedlaethol Cymru Health and Social Care Committee / Y Pwyllgor **lechyd a Gofal Cymdeithasol** Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol Evidence from Medical Defence Union - MIB 03 / Tystiolaeth gan Undeb Amddiffyn Meddygol - MIB 03

MDU Services Limited One Canada Square London E14 5GS

> w themdu.com

Mary-Lou Nesbitt Head of Governmental & External Relations Telephone: Mobile:

Email:

Date: 23 December 2014

Dear Mr Rees

Mr David Rees

Chair

By email

Re: Medical Innovation Bill

Health & Social Care Committee National Assembly for Wales

Thank you for inviting a submission from the Medical Defence Union about the Medical Innovation Bill.

The MDU does not support the Bill. The law in England and Wales is already very clear and there is no need for new legislation. We fear that the Bill will only serve to introduce confusion and delay in circumstances where they do not currently exist and that could be harmful for patients. The submission below is taken from the MDU's briefing ahead of the report stage of the Bill and begins by explaining the MDU's expertise and experience in this area before describing our concerns about the Bill. We hope it is helpful.

MDU experience of clinical negligence claims

The MDU is a mutual non-profit making organisation owned by our members who include around 50% of the UK's GP and hospital doctors. We provide medico-legal benefits including assistance with and indemnity for clinical negligence claims arising from clinical practice to GPs and doctors in independent practice. We also provide medico-legal advice and if the Medical Innovation Bill were to become law we would expect members to seek our advice about its correct interpretation.

Although the Bill has been comprehensively amended, our principal concern remains that there is no need for such a Bill. If there was a gap in the law that left doctors unprotected and prevented them from innovating in the interests of patients, we would support the Bill. Indeed we would have been clamouring for legislation on behalf of our members and their patients a very long time ago. However, our experience of clinical negligence litigation makes it clear to us there is no need for the Bill. We cannot support it because it would not aid innovation but would be more likely introduce confusion and delay where they do not currently exist. This would be to the potential detriment of our members and their patients.

The current law and ethical (GMC) guidance is clear – there is no need for a Bill The indemnity the MDU provides for medical members extends to innovative treatment. It is well recognised there must be departures from accepted practice so that medicine can evolve

and develop, and the current law and ethical requirements do not prevent that. There is no gap and the law is already very clear. There is no need for a Bill. Our medico-legal experience leads us to believe new legislation would only add confusion and delay while doctors got to grips with yet another piece of legislation affecting their clinical work. This is not in patients' interests and contrary to what the Bill proposes to achieve.

Potential for delay - a particular concern in emergencies

A serious concern is that the Bill proposes to introduce a defined procedure with which doctors will be unfamiliar. In some cases this may not be in patients' interests because it could prevent doctors from providing innovative treatment, while they check whether what they propose is compliant with the Bill; whereas currently they know what to do and, with the patient's consent, get on with it without delay. This is particularly important because the Bill does not cover emergencies. In an emergency, doctors know they must act in their patients' best interests. The Bill does not prevent that but it is silent on the matter. However, delay could be fatal if doctors believe innovative treatment is necessary but delay in order to seek advice about the Bill's requirements.

Background

During 2013, the MDU's advisory team answered over 33,000 calls from members, and our claims handling team opened 20% more medical files than in 2012. Even with all this activity, there is no evidence to suggest there is or that our doctor members believe there is lack of clarity or certainty about the circumstances in which they can innovate without fear of litigation. Enquiries about innovation are not common but the MDU receives a few each month. Members generally ask about consent and how much information patients need, as well as asking about GMC guidance, for example about the use of unlicensed drugs. Generally calls do not relate to innovation through surgical or other invasive procedures but cover practice the Bill does not mention, such as moving away from face-to-face consultations and exploring use of computer consultations or apps, or setting up web-based discussion forums. Members principally seek advice about ethical matters and their legal concerns are generally about compliance with data protection legislation.

Our experience is that if it is a doctor's clinical opinion that it is in a patient's best interests to try innovative surgical or medical treatment, and he or she has discussed the proposed treatment fully with the patient and answered all questions, and complied with any research protocol, doctors go ahead. If problems arise they are not particular to innovation but medicolegal problems that can arise in all cases: for example the patient did not fully understand the proposed procedure and was unhappy with the outcome, or the surgeon was unfamiliar with the technique and made a mistake, or there was a problem with the dose of the drug.

With best wishes

Yours sincerely Many hun Wersitt

Mary-Lou Nesbitt

Head of Governmental & External Relations