



National Assembly for Wales / Cynulliad Cenedlaethol Cymru  
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[Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad](#)  
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Evidence from Royal College of Physicians - MIB 05 / Tystiolaeth gan Coleg  
Brenhinol y Meddygon (Cymru) - MIB 05

# Legislative Consent Memorandum: Medical Innovation Bill

## RCP (Wales) evidence

### Key points

- The RCP welcomes the overarching aims of the Medical Innovation Bill and subsequent debate. However, the RCP does not support the progression of the Bill in its current form. Instead, the RCP calls for:
  - **Mandatory reporting** - the Bill should be amended to ensure that all results of innovation must be centrally recorded, reported and be publicly accessible
  - **'Responsible doctor'** - statutory guidelines outlining how a 'responsible doctor' should consider medical opinions should be developed
  - **Peer review** - more robust safeguards should be put in place to prevent doctors from innovating inappropriately
  - **Safeguards and promotion of innovation** - we support the statutory best practice checklist as a safeguard against irresponsible innovation
  - **Communication** - a clear implementation strategy should be developed which ensures the Bill is understood by the profession and the public
  - **Removing existing barriers to innovation** - alternative routes to achieving the aims of the Bill should be explored

For more information, please contact:

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**Dr Andrew Goddard FRCP**

09 January 2015

Dear colleague,

Thank you for the opportunity to respond to your consultation on the Legislative Consent Memorandum in relation to the Medical Innovation Bill.

### **About us**

The Royal College of Physicians (Wales) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in Wales and across the world with education, training and support throughout their careers. As an independent body representing 30,000 fellows and members worldwide, including 800 in Wales, we advise and work with government, the public, patients and other professions to improve health and healthcare.

### **Our response**

The RCP welcomes the overarching aims of the Medical Innovation Bill and subsequent debate. However, the RCP does not support the progression of the Bill in its current form. Without amendments to the Bill to include mandatory recording of the results of all innovative treatments, the RCP believes that the Bill will not achieve its stated objectives of encouraging responsible innovation while protecting patients and clinicians from irresponsible actions. Suitable safeguards must be put in place, both for the clinician and the patient.

For example, the current wording of the Bill does not place a duty on clinicians to record, review or share the results of innovative treatments. This significantly undermines the accountability of the innovation process, the ability to provide safeguards to clinicians and patients, and the process of sharing learning from innovation. For this reason, the RCP will not support the progression of the Medical Innovation Bill unless it is amended to include the mandatory recording of all innovation treatments. We also urge clarity on how a 'responsible doctor' would be expected to consider the opinions of medical experts prior to undertaking an innovative treatment. In particular, we recommend:



## 1. Mandatory reporting

The RCP is very concerned that the legislation does not place a duty on clinicians to record the results of innovative treatments. Without the mandatory recording of results of innovation, clinicians will be unable to share learning; irresponsible innovation will be more difficult to prevent; and accountability structures will be undermined. Including mandatory reporting of results as part of the innovation process will further ensure that learning from innovation can be shared. This will prevent harmful innovative practices from being repeated and encourage learning from good innovation. Mandatory recording will further provide evidence that the processes for responsible innovation have been followed. Thus providing safeguards for both clinicians and patients

The RCP believes that the Bill should be amended to ensure that all results of innovation must be centrally recorded, reported and be publicly accessible. This must include both positive and negative results, information about small scale treatments and patient experience. Without the mandatory recording of results the public benefits of medical innovation will not be achieved. A clear strategy for achieving this must be developed if there is to be true innovation. The strategy must address patient confidentiality, accessibility, thresholds for reporting, and practicalities, such as the method of hosting the database and reporting results.

The RCP understands that Oxford University has agreed to facilitate the dissemination of information from innovation treatments. However, this information will be collected on a voluntary basis. Unless there is a mandatory duty for results of all medical innovations to be recorded, data will not be collected in sufficient numbers to achieve the benefits of the medical innovation. This duty must be accompanied by statutory guidance that includes details on the process of mandatory recording of results. The statutory regulations must reflect a process that addresses patient confidentiality, accessibility, thresholds for reporting and practicalities.

## 2. Responsible doctor

The RCP is concerned that the wording of Clause 1(3)(b) of the Bill, as amended at committee stage, does not sufficiently clarify the process of medical innovation. The current wording of the Bill states that the opinions of appropriately qualified doctors must be considered in a 'way in which any responsible doctor would be expected to take account of such views'. However, the RCP believes that this clause is too vague. It does not clarify how a 'responsible doctor' would be expected to consider these opinions. We urge the development of statutory guidelines outlining how a 'responsible doctor' should consider medical opinions and how the process will work.

## 3. Peer review

There must be more robust safeguards in place to prevent doctors from innovating inappropriately. These should include:

- a. Stronger requirements for robust peer and ethical review before commencing treatment
- b. Stronger assurances for patients, carers and families
- c. Continued and active support for referral into larger NHS clinical trials.

## 4. Safeguards and promotion of innovation

We support the statutory best practice checklist as a safeguard against irresponsible innovation. This could be supplemented by guidance designed to emphasise the benefits and mechanisms supporting innovation.

## 5. Communication

There must be a clear strategy for bringing any new legislation into operation, and ensuring its requirements are communicated to and understood by the profession and the public.

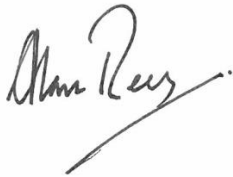
## 6. Removing existing barriers to innovation

The Medical Innovation Bill aims to create an environment that enables innovation and discourages irresponsible innovation. The RCP recommends that alternative routes to achieving these shared aims should be explored, such as opportunities to remove existing barriers to innovation, or improving and streamlining the funding and approval processes.

### For more information

If you have any questions, please contact our colleague, Lowri Jackson, RCP senior policy and public affairs adviser for Wales, at [REDACTED] or on [REDACTED].

With best wishes,



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Is-lywydd yr RCP dros Gymru



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