ACADEMY OF
MEDICAL ROYAL
COLLEGES

ACCESS TO MEDICAL TREATMENTS (INNOVATION) BILL

1. Purpose

The briefing sets out the views of the Academy of Medical Royal Colleges and its member organisations on the Access to Medical Treatments (Innovation) Bill.

2. Summary

Medical Royal Colleges do not believe that legislation is required. It is unclear what problem this legislation is seeking to resolve and uncertain that the proposals will achieve their stated purposes. More importantly, we have real concerns that the Bill will have unintended adverse consequences.

3. Background

The Bill picks up proposals first set out in the Medical Innovation Bill introduced in the last Parliament by Lord Saatchi. That Bill did not progress in the last Parliament. When it was first presented Royal Colleges and other professional medical bodies had concerns about the potential unintended consequences of the Bill. The amendments made to the Bill addressed a number of these concerns and were welcomed. However there still remained a danger of diverting efforts away from properly conducted clinical research. In summary, Medical Royal Colleges remained unclear as to what value the Bill would have added to the current position.

We have had discussions with Chris Heaton-Harris MP over his current Bill and are grateful to him for the opportunity for input and discussion. Medical Royal Colleges agree that research and innovation are vital to the NHS.

However we have also engaged with a range of other medical organisations and Royal Colleges still do not believe that this legislation is the right way to address what are important issues for the NHS.

4. Database of Innovative Treatments

Royal Colleges understand the theoretical attraction of establishing a database of innovative treatments. However we have serious concerns over:-

- *A register giving credibility to "innovations" which prove to be of no value and to the notion that proper clinical research or regulatory processes can be side-stepped*

We have concerns there is no quality control of the input to a register in terms of both veracity and completeness. If, for example, experience shows that an innovation is not effective is it then removed from the register? We are keen to see real rigour in registering of all clinical research in addition to clinical trials and their full methods and results reported. This proposal runs the risk of being used as an easy alternative. This is a threat to patient safety.

- *The practicality of establishing and running a register including protecting patient anonymity*

Current experience in the NHS shows that establishing an effective register for far more standard and straightforward procedures is a complex task. Establishing and maintaining a register of innovations would be a costly and potentially burdensome and bureaucratic task. In addition any register of, by definition, single procedures that is to be useful as a search engine by other doctors or patients (or their relatives) would need a degree of detail that risks compromising anonymity. We believe the practical difficulties in defining the data to be included, establishing and maintaining a register would outweigh any benefits and the costs involved would not be justifiable in current financial climate.

5. Responsible Innovation

The clauses in the Bill reflect those in Lord Saatchi's previous Bill. As with that, we believe that the Bill rests on the false assumption that it is fear of litigation that is holding back innovation by doctors. There is simply no evidence that this is the case and the Medical Protection Societies have made this clear.

The notes to the Bill state *"There is no requirement to follow the steps in the Bill. Doctors can instead rely on the existing common law, which allows a doctor to show that a responsible body of medical opinion supports his or her actions (the Bolam test), thus demonstrating that the individual was not negligent."* Following such an explicit statement we fail to see the purpose and need of these proposals and are concerned that the alternative approaches offered will simply cause confusion and uncertainty and undermine mechanisms already in place to safeguard patients.

6. Definition of Innovations

Colleges have serious concerns about the definition of innovation used in the Bill. Clause 5.2 states "*Nothing in this Act applies in relation to treatment carried out for the purposes of medical research."* We do not understand the distinction between "individual patient innovation" and "research". The distinction seems false and potentially dangerous. As a College President stated "*Innovation without research isn't innovation, it's more often just advertising."*

7. Conclusion

- Colleges wish to see patients benefit from medical innovation and have real concerns at the barriers to the initiation and spread of innovation in the NHS. The Government's own Accelerated Access Review led by Sir Hugh Taylor is addressing these issues and provides a more appropriate vehicle for solutions than primary legislation.

- We are keen to see real rigour in registering of all clinical research studies and their full methods and results reported; the proposed register risks undermining this aim.

- The practical difficulties in establishing a register, including maintaining confidentiality, outweigh the advantages

- Innovation cannot, and indeed should not, be separated, from research - which is what the Bill does. There cannot be one system for research and another for innovation

- In conclusion, Medical Royal Colleges do not believe that the Bill should be supported.