Access to Medical Treatments (Innovation) Bill

Guidance Note

1. This guidance note has been prepared in order to assist the reader in understanding the Access to Medical Treatments (Innovation) Bill.

The Bill does 2 main things:

- gives a regulation making power to enable the creation of a database of innovative medical treatments and to enable doctors to access information on the database; and

- provides an *option* for doctors who innovate to take steps in advance of carrying out an innovation, to show that they are acting responsibly (and thus not negligently). 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.

Innovative Medical Treatment

2. This is defined as a departure from the existing range of accepted medical treatments. Doctors will be the best placed to judge if they are departing from standard practice. The Bill does not apply to the use of treatments in research, for example as part of a clinical trial. It is concerned with individual patient innovation.

The database

3. **Clause 2** allows the Secretary of State to make regulations enabling the Health and Social Care Information Centre to establish a database containing information about innovative medical treatments and their outcomes. The database will cover all individual patient innovations, not only those where the doctor has chosen to rely on the steps under the Bill to demonstrate they have acted responsibly. The clause also allows provision to be made for access to the database, for example, by other doctors.

Responsible innovation

4. **Clause 3** sets out the steps which a doctor will need to take in order to show that he or she has acted responsibly under the Bill. They are intended to reflect as closely as possible the steps under the current common law which a responsible doctor could be expected to take when innovating. The Bill envisages that a doctor would obtain the views and support of a responsible body of medical opinion **before** innovating so that he could proceed to innovate confident in the knowledge that he has such support and thus will not be found negligent – provided he or she has followed the steps in the Bill which show that he or she has acted responsibly.

5. The views obtained by the innovating doctor in respect of the proposed treatment must be from "appropriately qualified doctors", i.e. with appropriate expertise and experience in dealing with patients with the condition in question. Further, the innovating doctor has to take full account of those views in a way which could be expected of a responsible doctor. If an appropriately qualified doctor were to express reservations about the proposed treatment, the innovating doctor could not disregard those reservations or give them little weight without a clear risk of being found negligent.

6. The aim of these provisions is to preserve the existing safeguards of the common law for the patient whilst giving the innovating doctor the additional choice of taking steps to evidence that he or she has acted responsibly in advance of carrying out the innovation.