

**MINISTERIAL MEDICAL TECHNOLOGY  
STRATEGY GROUP (MMTSG) MEETING 20 MAY 2009**

**ITEM 2 - Minutes of last meeting (25 November 2008) and  
matters arising  
(for approval / noting)**

**Minutes**

1. Draft minutes of the last MMTSG meeting held on 25 November 2008 (see attached) have been agreed by the Co-Chairs and are presented to the Group for formal approval.

**Matters arising (not covered elsewhere on the agenda)**

***Recast of the Medical Devices Directive (MDD) - Update on developments***

*Background*

2. The European Commission issued a public questionnaire in May 2008 to gather views on possible changes to the medical device regulatory regime. The questionnaire contained a mix of expected changes with other more far reaching and controversial ideas. These ranged from extending the scope of the current directives to include products not currently regarded as devices such as aesthetic fillers, to the introduction of a system operated by the EMEA for central market approval for certain undefined "high risk" medical devices.

3. The UK replied to the questionnaire in July 2008. While welcoming the more sensible and un-contentious ideas, for example merging current directives into a single text and the introduction of a risk-based classification system for in vitro diagnostic medical devices, we rejected the more controversial ideas on the grounds that they were not needed, could harm industry, deter innovation and damage patient health. We also made a number of positive suggestions to tackle the accepted shortcomings of the present system. These included a full review of the In Vitro Diagnostic Medical Devices Directive, the introduction of mandatory Peer Review for Notified Bodies and Designating Authorities, and the creation of a statutory Management Committee capable of making binding decisions to improve the consistency of interpretation and implementation of the various Directives across the EU. At the same time we declared ourselves keen to work with the Commission and others to progress the exercise.

4. The Commission originally hoped to issue firm proposals for negotiation during 2009. However, this has now been delayed until 2010 (at the earliest).

*Action since the questionnaire exercise*

5. The Commission is currently studying the responses (over 200) to its questionnaire. Most were broadly along the lines of that submitted by the UK.

6. To try to influence future thinking in this area, the UK authority has had a number of meetings with UK and EU industry trade associations to explore the practicalities of the various changes we have suggested. Industry is very supportive of these. MHRA also initiated a meeting of like-minded Member States in January 2009 to secure their agreement to the UK's ideas in advance of a meeting of all Member States in Prague held in February. At this later meeting we were able to put forward our ideas for necessary improvements in a very positive way and secure a wide measure of support. This resulted in a further meeting in Prague in April to flesh out the ideas more fully. The intention is to make a series of formal presentations to Member States at their next collective meeting in July under the aegis of the Swedish Presidency. Subject to agreement being obtained at that meeting (which is expected), we would seek to initiate full discussions with the Commission.

***Health Innovation Council (HIC)***

7. HIC has made an important contribution to the development of the innovation commitments in *High Quality Care for All*. We are in the process of refreshing the role and membership of HIC as work to deliver the out puts of the report is being forward.

***Company database***

8. Good progress has been made on developing the Bioscience and Health Technology Database. The contract to build and populate the database was awarded to Cels Business Services Limited (CBSL) in early March 2009 following a tender process using the OJEU two stage system. Of the five tenders submitted, CBSL's tender was the most economically advantageous against the chosen criteria, with a major strength being their detailed knowledge of the two sectors concerned – biotech and medical technology manufacturers.

9. The first meeting of the Industry Advisory Group (IAG), comprising key stakeholders from the national and regional support networks, and representatives from the RDAs and Devolved Administrations, took place on the 1 April 2009. Advice on how the sectors should be segmented was provided and Data Partners have now been asked to supply any information that they hold.

10. The database will be built and populated by the summer with the first analysis and commentary being produced in the autumn 2009.

**Joint Secretariat  
May 2009**