MMTSG/11/04

MINISTERIAL MEDICAL TECHNOLOGY STRATEGY GROUP (MMTSG)
EIGHTH MEETING 20 June 2011

Attending:

Government members		
Lord Howe (co-chair)	Parliamentary Under-Secretary of State for Quality	Department of Health
Rt Hon David Willetts MP	Minister of State for Science & Innovation	Department of Business, Innovation and Skills
Industry Members		
Colin Morgan OBE (co-chair)	Regional Vice President	Johnson & Johnson MDD
Bettina Fitt	General Manager UK & Ireland	GE Healthcare
Johnny Lundgren	Vice President, NW Europe	BD (also Chairman, ABHI)
Ewan Phillips	Chief Executive	Deltex Medical Group plc
David Plotts	Vice-President of Marketing	General Surgery, Covidien
Tony Davis	Chief Executive	Medilink West Midlands
Peter Ellingworth	Chief Executive	ABHI
Doris-Ann Williams MBE	Director General	BIVDA
Government invitees		
Christine Bloor	Director, Life Sciences team	Department for Business, Innovation and Skills
Sir Ian Carruthers OBE	Chief Executive	NHS South West
Richard Carter	Branch Head, Industry Sponsorship	Department of Health
Giles Denham CBE	Director of Medicines, Pharmacy and Industry Group	Department of Health
Jonathan Mogford	Director of Policy	Medicines and Healthcare products Regulatory Agency
Louise Wood	Deputy Director, Research & Development Directorate	Department of Health

Secretariat

Andy Taylor	Director - Healthcare Policy	ABHI
Simon Hiller	Section Head, Medical Technology	Department of Health
Edmund Hair	Life Sciences Policy Officer, Industry Sponsorship	Department of Health

Apologies

David Horne	Managing Director	Alere Ltd (also Chairman, BIVDA)
Harry Keenan	UK General Manager	Baxter Healthcare
Herb Riband	Vice President External Affairs International	Medtronic International

Item 1. Chair's opening remarks and introductions

1. Colin Morgan welcomed all those attending and wished to record thanks to industry side members of MMTSG who had stepped down: Simon Cartmell, Martin Jamieson and Philip Salt. Apologies were noted as above and the smaller size of the resulting meeting was welcomed. Earl Howe welcomed Johnny Lundgren of BD, new Chairman of ABHI, together with Ewan Phillips, to their first meeting and wished to record thanks to Gary Stapleton of 3M, who had now left the UK, for his past contribution both to the group and to wider relationships. It had been an exceptionally eventful period since the previous meeting. Whilst this meeting was strategically focused, it was complemented by regular interactions on specific issues in the interim.

2. Colin Morgan noted that a receptiveness to innovation would be essential for the success of the modernised NHS; and that demand-led innovation would be key. It would be important to avoid approaching challenges as they had always been approached, whilst expecting different results. The challenge for the group was to help guide on what should be done differently.

Item 2. Minutes of 17 November 2010 meeting

3. The minutes of the previous meeting were approved. The group briefly reflected on the action points arising from the last meeting. Industry's input into PbR developments was continuing, though plans for the future tariff remained uncertain . Both meetings alluded-to in the minutes - concerning procurement and regulation of in-vitro diagnostics - had taken place, and were considered helpful. Doris-Ann Williams commented that some of the questions raised in the latter meeting had proved outside the

scope of MHRA - as they concerned commercialisation of NHS activity – and it was agreed that these points should be picked up in other, more appropriate fora.

Item 3. The Plan for Growth – implementation

4. Earl Howe commented on the thoughtful inputs to the development of the Plan for Growth that had come from both trade associations and companies. Industry views had been influential in shaping the resultant package of sixteen actions, which included measures in support of research, procurement from SMEs and uptake measures. The minister noted in particular the NHS Chief Executive's report on innovation, to be published in November. The focus was to be on implementation, and the Government had put in place mechanisms to deliver.

5. David Willetts said that the departments had worked together and would be held to account for delivery. In BIS, there was an emphasis on tax, where further views were welcome, and on linking up strands of funding for research and translation, by bringing together the budgets across R&D and the research councils (MRC, TSB). The minister noted that UK has a world class research base, and the NHS a worldwide reputation. The key challenge was to link this with success for industry, given a history of being a 'late adopter of technologies first developed in the UK'.

6. Colin Morgan commented that the commercialisation of technologies was the central challenge for the MMTSG. He invited Sir Ian Carruthers to comment, who supported the Minister's views (declaring his interest, as a non-executive director of a device company). As with cardiac care for example, there was a measurable, fourteen year gap between publication of research data and best practice becoming widespread. Sir Ian was supporting the Chief Executive in his review of NHS innovation and there would shortly be a call for evidence, due to close at the end of August, to which he welcomed industry contributions. The focus of the report would be on what could be done to deliver rapid, appropriate adoption and diffusion of technologies at scale and pace, to better promote UK plc as well as the NHS. He expected that the review would form its initial conclusions by mid/late September and that it would be a co-production from all those who were involved. Invitations to the expert group would go out shortly including to some members of MMSTG. The expert group would be shadowed at official level and MMTSG would be kept up to date and involved.

7. Johnny Lundgren reinforced an industry view that NHS promotion of innovation was central to commercialisation in the UK for companies. Sir Ian commented on the absence of systematic processes and culture to support this, noting the difficulty in breaking into what is a fragmented

system. He would be wanting to continue his conversations with industry to identify what could change this.

8. Colin Morgan said that this was part of a range of issues, which also included access to finance for (especially) smaller companies and was related to the 'cost to serve'. Ewan Phillips reinforced this. He said that equity funding was not easily available for small companies and, if unable to sell to the NHS, this was even more so. Further, poor payment reduced SMEs' working capital for which they were invoiced by banks. Tony Davis noted that the larger private providers were extending payment terms to 60-90 days, which made these conditions even more difficult to deal with and could be 'life or death' for SMEs. Peter Ellingworth noted that these issues had been communicated to DH and a response was awaited.

9. In summarising this part of the discussion, Colin Morgan said that the strategic opportunities were recognised but short term barriers persisted. It was not an issue simply for smaller companies as they were part of an ecosystem involving also the larger companies.

10. Earl Howe said that he understood the importance of delayed settlement and that this would be an important issue for the NHS to address, given that guidance was clear and that there were checks in place, as Sir Ian also noted.

11. Another point to address was the gap between research and commercialisation where, as Louise Wood noted, the Plan for Growth introduced measures to support partnerships for translation. Industry should expect to see a more 'research-active' NHS. Colin Morgan welcomed this and looked for an environment which would take into account the engineering aspects of med tech development.

12. David Willetts suggested that a particular sector such as telemedicine might provide an opportunity to look at why developments were easier in, for example, California than in the UK, taking into account a research-friendly environment, quality standards for patients (with the NHS Constitution providing a mechanism enabling patients to challenge). In that context, he expected that the UK ought to be able to move more quickly than the US, though it would be wise to avoid the degree of litigation that appeared common there.

13. Colin Morgan noted the importance of the sound regulatory regime in Europe, enabling more rapid adoption of innovation than in the US. Jonathan Mogford commented that the relatively straightforward route for market access enabled a rapid pathway from innovation to diffusion and was good for European leadership in global terms. It would be important to maintain this in the revision of the directives. Colin Morgan commented

that commercialisation of R&D originated technology was however probably easier in the US.

14. Peter Ellingworth said that Government support for British businesses in export markets was essential. Whilst this was broadly in place, he felt that it needed some prominence on this agenda and with the Office for Life Sciences. The meeting agreed that ensuring UKTI representation at the Senior Industry Group and at the next MMTSG meeting would allow the point to be further addressed. Tony Davis commented that support would be helpful across the less fashionable markets that SMEs worked in, as well as in North America. The BRICs markets remained however relatively small in relation to those in the US and Europe.

15. The level of bureaucracy encountered by SMEs in selling into the NHS was raised, particularly in respect of contract Terms & Conditions (T&Cs) and Pre-Qualification Questionnaires. Industry members commented on comparable issues with NHS Supply Chain, which had changed T&Cs against long-standing arrangements. Colin Morgan commented on the length of time over which this had been taking place without resolution and said that there should be a core set of T&Cs which did not have to be constantly re-invented. Lord Howe undertook to make Simons Burns (the DH Minister with responsibility for procurement) aware of these concerns.

16. Summing up, there was broad agreement that telemedicine might offer helpful insights, spanning as it would so many boundaries. Sir Ian Carruthers did not want the Chief Executive Innovation Review to be seen as a panacea but agreed that progress in this field was likely to provide helpful learning.

Item 4. NHS Reform

17. Earl Howe introduced this item and said that the report of the Future Forum had been invaluable in focusing attention on important areas of implementation, which would be reflected in a recommitted Bill which would also respond to the results of Parliamentary scrutiny to date. Many of the key recommendations of the Future Forum had been accepted and he summarised the main areas which would be altered, including:

- The role of clinical senates to provide expertise in the design of patient pathways with clinical commissioning groups and more prescription about governance in general as regards clinician expertise involvement.
- Redefinition of Monitor's core duties to make it clear that the 'market' remained controlled, with patient care interests at its heart. Monitor would bear down on conflicts of interest and be a guardian of fair competition.

- The Bill was neutral as regards ownership of providers – but competition would be mobilised to best meet the needs of patients. Quality was the central principle, with patient involvement and choice remaining a key emphasis. The approach would be evolutionary rather than revolutionary.
- An emphasis on joining up patient pathways for integration between health and social care had been absent and this would be changed.
- A duty for innovation and research, in the original bill, was replicated for the clinical commissioning groups, with a clear chain of accountability.
- There was a greater emphasis on the NHS Constitution.

In summary, the bill had been made more coherent. Timings had been changed better to allow for transition, eg SHAs would continue for an additional year. There were changes to make certain features clearer, for example the new arrangements would not fall foul of or expand the reach of European competition law. The overall heading of the bill had been changed and the duty to provide a comprehensive health service remained with the Secretary of State for Health.

18. In response to a question from David Plotts about how industry might contribute to the changes, over and above through device technology itself, Earl Howe said that the Commissioning Board would want to ensure good relations through arrangements it was planning to set in place. Sir Ian Carruthers said that the innovation review report he was leading on would be addressing this question and look ahead beyond 2013. Ewan Phillips commented on the difficulty of implementing even technologies where evidence was firm. Earl Howe said that the clinical commissioning groups would need to see across such silos and 'comply or explain' with established evidence. HealthWatches would help hold them to account.

19. Colin Morgan welcomed the Minister's summary and said that the transition was a major challenge in the short-term with the immediate landscape very difficult all round. Education and training would be fundamental for the medtech industry, and Mr Morgan was pleased to see they these two important topics would be a focus of the next stage of the Future Forum's work.

Item 5. Revision of the EU regulatory framework for medical devices

20. Earl Howe said that a proposal on the recast was now expected for early next year. Whilst the current system was broadly sound, it could be improved to enhance safety for patients and to foster innovation across Europe. Jonathan Mogford said that there was an emerging view of what was needed:

- Better oversight of Notified Bodies, with tighter control of what they are authorised to approve according to proven expertise and competence.
- How to improve post-market surveillance whilst also making market access easier.
- How to coordinate better across Europe. The heads of agencies were working together well but needed to be linked with properly resourced institutions.

21. Peter Ellingworth welcomed this summary and said that the industry wanted to resist a drift to management by the European Medicines Agency and a risk of disproportionate regulation. Jonathan Mogford noted that it was clear that we were not moving to a pharma-type system. Colin Morgan commented that the discussion between industry and regulators had been open and helpful.

Item 6. Closing remarks

22. Colin Morgan said it had been a very helpful meeting and thanked all participants for their candour. There were action points around telecare/medicine, T&Cs and payment terms for NHS suppliers, and the industry's further response to the Future Forum; and UKTI would be invited to the next meeting.

23. Earl Howe noted that Colin's summary of actions illustrated how useful a meeting this had been, and stressed his eagerness to maintain the constructive and ongoing dialogue that he had witnessed to date.

24. The date of next meeting was agreed for 23 November 2011.