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## FOREWORD

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This supplement contains papers emanating from the MedtecHTA project, which was funded under the European Union FP7 research programme (HEALTH-F3-2012-305694; Project MedtecHTA ‘Methods for Health Technology Assessment of Medical Devices: a European Perspective’). The objective of the MedtecHTA project was to investigate improvements in health technology assessment (HTA) methods to allow for more comprehensive economic evaluation of medical devices.

Medical devices present several challenges for HTA and economic evaluation. First, they have traditionally been less regulated than pharmaceuticals, and the amount of evidence collected for licensing medical devices is generally lower. The EU directive in 2007 (2007/47/EC) made some significant changes in this respect by recognizing that it is necessary to enhance the provisions on clinical evaluation, including clarification that clinical data are generally required for all devices. Consequently, medical devices placed on the EU market or put into service after 21 March 2010 must be in conformity with these new requirements. However, in contrast to the requirements for pharmaceuticals, the studies can be small clinical trials or even nonrandomized clinical investigations, and long-term efficacy data are not required, thus reducing the knowledge base for subsequent HTA activities.

In addition, medical devices differ from other health technologies in a number of important respects: (i) they are characterised by incremental innovation and often change rapidly; (ii) the clinical outcomes obtained from the use of devices often depend on the training, competence and experience of the end-user (the so-called ‘learning curve’); (iii) pricing of devices is typically more dynamic than that of pharmaceuticals; and (iv) the use of devices often has organizational implications, such as the need for training and investments in infrastructure.

One major consequence of the less stringent regulatory framework and the challenges for conducting HTA is that the diffusion of medical devices often takes place ahead of the availability of the appropriate evidence. Coupled with the financial and other incentives operating in health care systems, there is a risk that the use of devices may be relatively uncontrolled. Therefore, the MedtecHTA project conducted several strands of research, addressing (i) the development of processes for the conduct of HTA and its closer integration with clinical assessment; (ii) the development of new methods for assessing the clinical and cost-effectiveness of medical devices, taking account of their special characteristics; (iii) the diffusion of medical devices in EU member states, including the influence of organizational characteristics and the associated evidence; and (iv)

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the methods of encouraging appropriate diffusion by linking decisions on reimbursement and coverage with evidence development.

The papers published in this supplement report on all these aspects of the MedtecHTA project and also reference the other published outputs from the project. Therefore, taken together, they represent a comprehensive report of the project's outputs.