Response to NHS Chief Executive’s Open Call for Evidence and Ideas

Respondent ID: 97

Organisation name: Medicines & Healthcare products Regulatory Agency

Type of response: Letter
Dear Sir Ian,

Thank you for your letter of 8 July 2011 about accelerating the adoption and diffusion of innovations across the NHS.

The Medicines and Healthcare products Regulatory Agency (MHRA) welcomes this initiative. Whilst the MHRA has its primary role of protecting public health through regulation of medicines and devices, the need to promote innovation is recognised in our aims and objectives and forms a key consideration for the work that we undertake. I have illustrated this below in relation to our work on clinical trials and the regulation of medical devices.

Clinical trials
The Clinical Trials Directive 2001/20/EC that came into force in 2004 has been the subject of significant concern amongst commercial and academic researchers since its introduction. The European Commission plans to bring forward legislative proposals to amend the Directive in the second quarter of 2012. The MHRA is actively lobbying the Commission to ensure that unnecessary administrative and regulatory burdens are reduced by providing a risk based approach to approval and to remove unnecessary obligations currently placed on researchers by the Directive.

The review of the Clinical Trials Directive has become an important issue for the Government: the need for the Commission to prioritise this review is referred to in the recently published Plan for Growth and was included as a key element of the recent Academy of Medical Sciences (AMS) review of the regulation and governance of clinical research. Also included in the Plan for Growth are commitments that MHRA will introduce a risk adapted approach to certain aspects of clinical trial regulation in advance of the review of the Clinical Trials Directive. The MHRA is in the process of implementing these commitments.
In order to improve implementation of the current Clinical Trials Directive the MHRA has undertaken a number of projects with the broad aim of applying a risk proportionate approach in the UK to the approval, monitoring and inspection of clinical trials where appropriate. A scheme has been in place since April 2011 to permit a notification scheme for low risk national trials which operates within the current Directive framework. Also, risk-proportionate monitoring has been introduced, taking a targeted approach to the monitoring of trials that depends on the risk they represent to patients and to data credibility. Using a set of guidelines and tools sponsors themselves determine the right level of monitoring required which is proportionate to the level of risks associated with the trial.

The MHRA has also set up an internal Steering Group to oversee the different aspects of clinical trials and to identify opportunities to improve regulation and lift burdens in order to make the UK a more attractive place for clinical trials.

Medical devices
The medical device industry is acknowledged as an important contributor to improving public health protection, and represents a valuable global market with significant potential for growth. It forms part of the life sciences sector, and was included in the first phase of the Government’s Growth Review. In Europe, medical devices are regulated under three core Directives – these are single market measures based on the New Legislative Framework, meaning that there is full harmonisation in the sector across the EU.

The European Commission is currently in the process of developing proposals to revise these three Directives. The MHRA is clear that one of the major strengths of the current Directives is the ability to combine a relatively light-touch regulatory approach, which helps foster innovation in the sector, whilst also delivering a high level of public health protection. The MHRA has been working alongside industry and other Member States to help shape the Commission’s proposals and ensure that the weaknesses identified within the system are addressed, without increasing regulatory burden unnecessarily or hampering innovation within the sector.

In both of these – and many other – areas the MHRA works closely with the Department of Health, the NHS, across Government and with industry to develop our approach. We recognise that some of the actions from the call for evidence in this area may fall to the MHRA, and we look forward to taking this work forward in the same way.

Yours sincerely,

Professor Sir Kent Woods
CEO