

# NHS European Office

## Annual Report 2009/10

### Introduction

The NHS European Office was established at the end of 2007 to represent NHS organisations in England to EU decision-makers. The Office is funded by the Strategic Health Authorities and is part of the NHS Confederation. The work of the Office includes:

- monitoring EU policy and legislative developments which are important to the NHS
- informing NHS organisations of EU affairs
- influencing EU proposals in the interest of the NHS
- promoting NHS expertise to EU decision-makers
- advising NHS organisations of EU funding opportunities.

This report presents the main activities carried out by the NHS European Office in the 2009/10 financial year. It is structured around the following sections, reflecting the areas of work in the Office's work plan:

1. EU policy and legislation – monitoring and engagement (page 1)
2. Communication and NHS engagement (page 7)
3. Raising the profile of the NHS and promoting NHS good practice to EU decision-makers and stakeholders (page 8)
4. Innovation and EU funding programmes (page 9)

### 1. EU policy and legislation – monitoring and engagement

This section provides an overview of the work carried out by the European Office to engage with EU policy and legislation and, in particular, to influence them in the interest of the NHS. It is structured around key policy priorities identified in the Office's work plan for 2009/10, but also includes information on other EU initiatives with which we have significantly engaged.

#### Cross-border healthcare

EU discussions on the draft directive on patients' rights in cross-border healthcare, which aims to clarify the rights of patients to travel to other European countries to receive medical treatment and the responsibilities of health systems to facilitate and fund this, have continued throughout the year.

The Office continued its work with Members of the European Parliament (MEPs), briefing them on NHS views, in particular in relation to their proposals for amendments, in the run up to the votes both in the relevant Committee and in the plenary of the full Parliament. However, following the adoption of the Parliament's First Reading Report, progress has been slow and discussions in the Council of Ministers have stalled.

The Office is monitoring developments in the Council with a view to being ready to engage with decision-makers when discussions resume. In the interim, we have continued to advance NHS views and brief a range of stakeholders on the potential implications of the proposals.

In parallel, the Office has worked closely with the Department of Health's (DH's) cross-border implementation team on activities aimed at promoting awareness of the existing legal framework, adapting current UK regulations and preparing for implementation of the future directive, if it is agreed. We have also continued our work with the DH's overseas healthcare team and NHS colleagues to promote awareness of the European Health Insurance Card, and in particular to highlight changes to the arrangements for European Economic Area visitors requiring emergency treatment from the NHS.

### **Patient safety and quality of healthcare**

Following the adoption of the Council Recommendation on patient safety and healthcare associated infections in June 2009, which the Office successfully influenced in the interest of the NHS, EU activities on patient safety have taken a broader focus, extending to incorporate discussions on the quality of healthcare. The Office has remained highly engaged in this work, both through input to DH policy leads and through our membership of the European Hospital and Healthcare Federation, which sits on the EU Patient Safety and Quality of Care Working Group.

The working group has been considering a 'discussion paper' drafted by the European Commission on quality of care, which looked at a range of options for EU activity in this area. The Office has contributed views on this paper and will continue to engage with this work as it progresses.

### **Organ donation and transplantation**

The Office has monitored discussions in the European Parliament and the Council of Ministers on the draft directive on quality and standards of organs for transplantation with a view to ensuring that, insofar as possible, the proposals complement existing UK arrangements.

As the European Parliament's examination of the proposals got underway, we worked closely with DH officials to assess the impact of amendments proposed by MEPs. We then collaborated with both DH and the European Hospital and Healthcare Federation to ensure a coordinated approach in briefing MEPs ahead of the vote in the relevant Committee. We will continue this approach as discussions progress over the coming year.

### **Pharmaceutical package**

The Office has continued to monitor and engage with the package of proposals on pharmaceuticals released by the European Commission at the end of 2008. We have in particular focused on the proposed directive to regulate the provision of information to patients on prescription-only medicinal products, which has proven highly controversial.

We have made key EU decision-makers aware of our views on these proposals and have liaised with the Medicines and Healthcare products Regulatory Agency (MHRA) and with Brussels-based interest groups to exchange views and collaborate.

The Office has also engaged with EU proposals on falsified medicinal products and pharmacovigilance (monitoring the safety of medicines). On the former in particular, we have worked to ensure that countries are able to decide at national level on a risk-assessed and case-by-case basis what safety features should be required for non-prescription medicines. We have also advocated allowing stricter safety measures already existing in Member States to be maintained.

We will continue to liaise with MEPs and stakeholders on all these aspects of the package as the legislative process continues in 2010/11.

### **Clinical trials**

The NHS European Office coordinated a response to the European Commission's consultation to assess the functioning of the existing EU Clinical Trials Directive. Whilst it is widely accepted that the Directive (implemented in 2004) has improved the safety and ethical soundness of clinical trials across the EU, a number of issues have emerged contributing to make the UK a less attractive location to carry out clinical trials. Researchers in NHS organisations have brought to our attention weaknesses with regards to the current system and have called on the NHS European Office to actively engage with a possible review of the EU rules.

This consultation sought views on the functioning of the legal framework and the possible options for remedying shortcomings and unintended consequences that have become apparent since its introduction.

Our response called for a more streamlined approach to clinical trials across the EU and for a system that is proportionate to the risk. We also recommended a faster approval process, fewer variations in the way guidelines are interpreted in different countries, and a reduction of the administrative burden. The consultation will inform possible EU proposals to review the Clinical Trials Directive expected in 2010/11.

### **Restriction on the use of hazardous substances in medical devices**

In 2008 the European Commission published proposals to review the EU Directive to restrict the use of certain hazardous substances in electrical and electronic equipment.

The review proposed to remove the exemption for medical devices from the scope of the Directive, and to put forward a series of staggered deadlines by which time medical devices containing hazardous substances could no longer be placed on the market.

The NHS European Office has worked closely with the Department for Business, Innovation and Skills (BIS) and the MHRA to develop its position on the Commission's proposals. We have also held a series of meetings with key MEPs to discuss the proposals and suggest changes to the text to ensure that the provision of high quality and safe healthcare will not be jeopardised by these rules. Work on this dossier will be ongoing in 2010/11.

### **Energy performance of buildings**

New EU rules on energy performance of buildings were recently agreed. The rules aim to help Europe achieve a 20% reduction in energy consumption by 2020 and place particular emphasis on the public sector.

The NHS European Office carried out a broad range of activities to influence these proposals. In particular, we briefed MEPs and the leading government department (including responding formally to their consultation) on NHS views and proposed a number of changes to the text of the draft Directive.

NHS views were taken on board by decision-makers particularly with regard to getting buildings not frequently visited by the public excluded from the energy certification and display requirements of the Directive. This was a concern in particular for Ambulance Trusts, which have several such buildings, and were worried about losing the flexibility to

use resources intended for energy awareness and efficiency in ways they deemed most effective.

We were also successful in achieving a more feasible timetable for implementing the new requirements, particularly with regard to the energy certification of buildings, and a requirement for stakeholder consultation on the implementation rules.

The EU law is expected to be formally approved (without changes) in the course of the next few months. Following formal adoption, national governments will have two years to bring national laws into line with the new EU Directive.

### **Industrial pollution**

The European Commission proposed a revision to the Integrated Pollution Prevention and Control Directive, which is intended to clarify and strengthen the existing European legislation on industrial pollution. A key change proposed is the extension of the scope of the legislation to cover smaller combustion installations, which means that despite the proposal's emphasis on industrial emissions, around 70 NHS hospitals across the UK would be covered by this legislation for the first time.

We consulted all hospitals potentially affected and it emerged that these proposals would create a disproportionate burden, as hospitals would become subject to the rules because of their need for standby capacity and therefore their potential to emit, rather than their actual emissions.

Accordingly, we informed EU decision-makers of our concern and proposed solutions. The EU decision-making process is still ongoing but to date our views have been reflected in the draft position of the European Parliament and of the Council of Ministers.

### **Hospitals' emissions**

The European Office successfully influenced the revision of the EU Emissions Trading Scheme (ETS) Directive in 2008/09 gaining an opt-out for hospitals from the scheme from 2013, subject to alternative domestic instruments which achieve an equivalent contribution to emissions reduction. The opt-out is designed to reduce the administrative and financial burden on hospitals, whilst avoiding any negative impact on the environmental integrity of national carbon reduction targets.

In the course of 2009/10 the Office worked closely with the DH and NHS trusts currently subject to the ETS to encourage the leading Government department (Department of Energy and Climate Change - DECC) to make use of this possible opt-out nationally.

### **Late payments in commercial transactions**

The Office has influenced a proposed revision of existing EU rules on late payments in commercial transactions. The proposals seek to tackle the culture of late payments within the public sector, through provisions limiting payment periods to 30 days unless duly justified and the introduction of a fixed flat rate late payment fee of 5% of the amount due.

At a time of budget restrictions, despite the overall good payment practice in the NHS, the proposals could have significant financial implications for the NHS given its high procurement budget.

We undertook a consultation exercise with NHS trusts where significant concerns were raised at what they saw as an arbitrary and disproportionate penalty, and an attempt to bring in an uneven playing field between public and private healthcare providers.

Working closely with BIS (the lead Government department), the DH and the Local Government Association (LGA) the European Office has informed EU decision-makers of NHS views and proposed a number of changes to the EU text, including the deletion of the 5% penalty. The decision-making process is still ongoing but EU decision-makers have so far shown support for our views.

### **Competition and public procurement**

The Office sought to complement the national policy debate on cooperation and competition throughout the year by providing information to NHS organisations on how EU competition and procurement rules apply to NHS activity.

Work included producing and disseminating a briefing on what EU competition rules mean to the NHS. The Office also published a briefing to raise awareness in the NHS of recent changes to the EU Public Procurement Remedies Directive and their potential implications.

In addition, we advised NHS trusts on preparing for implementation of the new EU law on public procurement of clean vehicles (the Office influenced these rules in the interest of the NHS during 2008/09). Finally, to assist the NHS in 'greening' its public procurement policies, the NHS European Office circulated EU guidance in the form of a 'Green Public Procurement Toolkit' to all NHS trusts.

### **Health professionals**

The European Commission's initiative on the European Workforce for Health, expected in late 2009 following a consultation earlier that year, was delayed pending further consideration. The NHS European Office has been monitoring discussions in the meantime and has been invited to participate in the 'policy dialogue' events which have now been arranged to take this work forward.

Alongside this, preparatory work ahead of a review of the Directive on the Mutual Recognition of Professional Qualifications, due to start in 2011/2012, has begun and the Office is engaging in this process to advance NHS views. In particular, we continue to promote the inclusion in a revised directive of a duty on professional regulators to share information. We have also begun to examine concerns raised by some partner organisations in relation to the rules on language testing and will continue this work in the coming year.

### **Working Time Directive**

Following the failure of EU negotiations on the revision of the Working Time Directive in 2009, further EU action in this area was postponed pending the European Parliament elections in June 2009 and the confirmation of the new European Commission in February 2010. Working with NHS Employers we have continued to monitor the situation and to feed into informal discussions with the Commission.

The European Commission has now decided to undertake a comprehensive review of working time regulation, and has launched a consultation of the EU social partners. The Office will coordinate NHS input to the European Centre of Enterprises with Public Participation (CEEP) and the European Hospital and Healthcare Employers' Association

(HOSPEEM) responses and will keep NHS organisations informed as the review progresses.

### **Electromagnetic fields / MRI practice**

The Office was involved in the drafting of HOSPEEM's and CEEP's responses to the European Commission's first stage consultation of the social partners on the possible revision of the Directive on the protection of workers from exposure to electromagnetic fields. Implementation of the Directive, originally due in April 2008, was delayed as a result of concerns about the impact on the use of magnetic resonance imaging (MRI), in particular, in the healthcare sector. The responses argued that strict exposure limits in the Directive should be revised due to the lack of evidence to support them and the negative impact for both patients and staff of limiting the use of MRI techniques.

We have also worked with the Alliance for MRI to highlight the issue to key EU decision-makers including, in particular, Members of the European Parliament. Following the results of the first stage of the social partner consultation, the European Commission is committed to further action in this area during 2010/11, and the Office will continue to engage in this process.

### **Maternity leave**

The NHS European Office has monitored discussions in the European Parliament on proposals to extend minimum provisions for pregnant and breastfeeding workers, and contributed to the Partnership of Public Employers' response to the UK Government's consultation on the draft proposals. We have also fed NHS views on the key issues raised by MEPs to colleagues leading the negotiations for the UK in the Council of Ministers, and successfully pressed for the European Parliament's vote to be postponed pending an impact assessment.

### **Health inequalities**

Following a public consultation earlier in the year, the European Commission adopted a communication on EU action to reduce health inequalities in October 2009. Our Office highlighted the publication to NHS organisations and assisted the EU Committee of the Regions' Rapporteur in the preparation of their report on the proposals.

### **Childhood immunisation**

The proposals on childhood immunisation, expected in 2009, were postponed, and it is not clear whether a new publication date is foreseen. However, in July 2009, the European Commission adopted a proposal for a recommendation on seasonal flu vaccination. This called on EU Member States to commit to reaching the goal of 75% coverage of older people and other at-risk groups by 2014/15 at the latest. The proposals were modified by the Council of Ministers prior to their adoption such that the goals remain an 'aim', which is consistent with the NHS position. The Office publicised the work on this recommendation. It also monitored and reported on wider EU action in connection with the H1N1 flu pandemic.

## **2. Communication and NHS engagement**

A key objective for the NHS European Office is to ensure that NHS organisations are informed of EU affairs. The detail below outlines the main activities undertaken by the Office to implement its NHS communication strategy in the course of the year:

### **Expert and Specialist Contact Groups**

In addition to its continued relationship with the EU leads within each SHA, the Office has built on and maintained contacts with networks of expertise in specific policy areas relevant to the Office's work plan. This has proved hugely beneficial in helping us to gauge the implications of EU proposals for the NHS and in informing our responses.

### **Presentations and events**

The Office gave a number of presentations to NHS organisations throughout the year, focusing on the role of the Office and EU policy developments of particular importance to the NHS. This has included presenting and exhibiting at various conferences and meetings of the NHS Confederation and its Networks, as well as at external events with NHS participation.

### **The website**

The Office redesigned its website creating a broad web-portal to inform readers of the structure and activities of the EU Institutions and the EU's role in health policy more generally, as well as highlighting the different policy areas of the Office's work plan, and encouraging interested parties to get involved in the work of the Office. The website ([www.nhsconfed.org/europe](http://www.nhsconfed.org/europe)) is now directly linked from the home or staff pages of many of the SHAs and other relevant organisations.

### **Bulletins**

The NHS European Office electronic bulletin was launched in May 2009 and distributed on a bi-monthly basis to around 2,000 contacts, the vast majority of which are senior NHS managers. It highlights EU developments of importance to the NHS and updates on the work of the Office. The Office has also continued to use the various news bulletins of the NHS Confederation and its Networks to disseminate EU news on a regular basis.

### **Publications and briefings**

We produced the following publications in the course of the year:

- What do EU competition rules mean for the NHS? (June 2009)
- Are you paying your bills on time? (June 2009)
- Making Clinical research less of a trial (November 2009)
- The new EU Remedies Directive: prudent procurement is of the essence (January 2010)
- NHS European Office policy priorities 2010 (January 2010)

In addition, other numerous briefings were disseminated by the Office to inform NHS organisations of different EU developments and gain NHS views.

### **Study visits**

The Office arranged NHS participation in study visits to:

- Spain, to learn about the Spanish organ donation and transplantation model, which is considered best practice across Europe.

- Estonia, to discuss the Estonian healthcare system and in particular their contract monitoring systems and planning of service provision, and good practice in ensuring cost control.
- Brussels, to learn and exchange experiences of innovation in healthcare across Europe in the context of the EU Open Days event organised by the European Commission and the EU Committee of the Regions.

The European Office also participated in a study visit to Brussels for regional PCT Chief Executives in October 2009. The visit was organised by the respective SHA as part of their leadership programme and aimed to provide Chief Executives with an insight of the wide range implications of EU affairs on NHS activity.

### **3. Raising the profile of the NHS and promoting NHS good practice to EU decision-makers and stakeholders**

The main activities carried out by the Office throughout the year include:

#### **Building relationships with the newly elected European Parliament**

Further to the European Parliament elections in Summer 2009, and the particularly high number of newly elected MEPs, we wrote to the UK MEPs and key MEPs from other countries to inform them of the expertise we can offer when EU policy and legislation are shaped. To help reinforce this message the Office produced an informative guide for MEPs.

This was followed by holding personal meetings with several MEPs and the organisation of visits to NHS organisations for some of them, as a way of informing them of NHS practices and building relationships. In particular, we organised for MEPs to visit:

- North East Ambulance Service NHS Trust in April 2009 to discuss EU affairs affecting the ambulance sector
- East of England Ambulance Service NHS Trust in January 2010 to discuss the implications for the Trust of the Late Payments in Commercial Transactions Directive and the Energy Performance in Buildings Directive
- the NHS National Innovation Centre to discuss innovation and procurement issues
- Imperial College NHS Trust in April 2010 to discuss NHS practices in organ transplantation.

#### **NHS participation at EU conferences and workshops**

Whilst the European Office itself participated in many EU events, in the past twelve months it also facilitated for direct NHS involvement as a way of promoting NHS good practice and the exchange of experience. In particular, this included:

- presenting on NHS information and communication technologies used in emergency vehicles at an event in Brussels in June 2009
- attendance at a high-level conference on young peoples' mental health organised by the European Commission and the Swedish Health Ministry in September 2009
- presenting on a regional health research and innovation strategy at a workshop during the EU Open Days event in Brussels in October 2009
- participating in a workshop on telemedicine in March 2010 in Brussels, addressing the legal and logistical issues in telemedicine practice across borders

- attending eHealth week 2010 in Barcelona, which for the first time saw the annual Ministerial eHealth conference merged with the World of Health Information Technology conference and exhibition
- speaking at a session of the European Health Forum in Gastein (Austria) on NHS good practice in public health in October 2009

### **Cooperating with EU stakeholders**

We have continued our cooperation with different EU stakeholder organisations and in particular the European Hospital and Healthcare Federation, as a way of promoting NHS good practice in Europe and allowing NHS organisations to benefit from the exchange of experience with their European counterparts.

Towards the end of the financial year the Office also started its involvement in the work of the EU social partner organisations CEEP (the European Centre of Enterprises with Public Participation) and HOSPEEM (the European Hospital and Healthcare Employers' Association) in view of preparing to formally take on responsibility for representing NHS employers on these organisations from April 2010.

Finally, the Office has cooperated with many different other EU organisations on an ad hoc basis in the context of EU policy work or specific initiatives.

## **4. Innovation and EU funding programmes**

The Office has developed its work in the field of innovation and EU funding opportunities over the past year. This has involved drawing parallels between NHS priorities in the field of innovation at regional and national level, and opportunities for engaging in EU activities including funding applications, cross-country partnership working, and participation in EU level events.

On innovation the Office has initiated and maintained contact with a range of UK and European stakeholders, including the Health Services Research Network, the Association of UK University Hospitals, the NIHR, the Medical Research Council, ERRIN (the European Regions for Research and Innovation Network), the European Forum for Good Clinical Practice, and the Ambient Assisted Living Network. We have also developed our links with the Department of Health's Research and Innovation leads, the National Innovation Centre, and the NHS Research and Development Forum.

We have worked with regional innovation hubs in England as well as other regions in Europe, to identify shared objectives and foster opportunities for cooperation between NHS organisations and their European counterparts.

With regards to EU funding opportunities, the Office has closely monitored EU programmes and informed NHS organisations of opportunities to apply for funding as they have arisen. This has included attendance at European Commission information days, and drafting and circulating briefings on calls for proposals under the following EU programmes: the Health, Environment and ICT strands of the EU Research Programme (called the 7<sup>th</sup> Framework Programme for Research and Development), the European Commission Health Programme, the Competitiveness and Innovation Programme (CIP), and the Innovative Medicines Initiative (IMI).

The Office has also provided detailed advice to a wide range of queries from NHS organisations on funding opportunities and project ideas.