the voice of the NHS in Europe

NHS European Office

Annual report 2017/18

Introduction

Inevitably, since the outcome of the EU referendum in June 2016, the focus of the NHS European Office's work has shifted dramatically. Our priority in 2017/18 has been to engage with stakeholders both in the UK and the EU to assess the impact of Brexit on the NHS, and to influence decision makers to prioritise the interests of patients and the healthcare and research they rely on during the Brexit negotiations.

In parallel to our Brexit related work, we also continued to engage with the more traditional EU agenda. We continued to monitor and engage with EU policy and legislative developments of key importance for the health service, ensuring that the NHS had a strong voice in the EU arena. We also carried on with our activities on EU funding programmes, informing and providing advice to the NHS on emerging EU funding opportunities.

This report provides an overview of the main activities that we conducted in the course of the last 12 months, in the following areas:

Assessing the impact of Brexit on the NHS

Monitoring and influencing EU policy and legislation in the interest of the NHS

Facilitating access to EU funds for NHS bodies and their partner organisations

Supporting pan-European collaborations and sharing of successful European best practice.

Assessing the impact of Brexit on the NHS

Throughout 2017, the European Office has been highly active and visible, issuing regular Brexit bulletins, press articles and blogs. We have given numerous presentations on the impact of Brexit on the NHS to a wide range of British stakeholders, including Health Education England's deans, the Council of Deans for Health, NHS Employers' Medical Workforce Forum, Mental Health Network, NHS R&D Forum, National Voices (patients' organisations), General Dental Council and Professional Standards Authority, and European organisations such as the European Hospital and Healthcare Federation (HOPE), the European Federation of Neurological Associations (EFNA), and representatives from Germany's regions.

To this end, we maintain close contact and exchange information on a regular basis with our government and agency counterparts dealing with 'Brexit' issues in the Department of Health, NHS England, Health Education England, Public Health England, NHS Improvement and the UK's Permanent Representation in Brussels.

European Reference Networks

We have given much support to UK NHS trusts who are coordinating and participating in European Reference Networks. Membership of these networks is currently dependent on EU/European Economic Area (EEA) membership, so they could be excluded from the networks post Brexit. We have ensured ERNs are included into the collective work agreed by the Brexit Health Alliance (BHA) and have assisted UK NHS coordinators to respond to relevant UK parliamentary inquiries on Brexit.

Brexit Health Alliance

In June 2017, the NHS Confederation launched the Brexit Health Alliance (BHA), which brings together the NHS in all four UK countries, medical research, industry, patients and public health organisations under one banner to ensure a good Brexit for health. The NHS European Office provides the secretariat for the alliance, which calls for:

- Preservation of **reciprocal healthcare** arrangements
- **Regulatory alignment** for the benefit of patients and population health
- Maximum levels of **research and innovation** collaboration
- Robust coordination mechanisms on **public health** and wellbeing
- A strong **funding** commitment to the health and public health sectors.

Since its launch, the alliance, which is chaired jointly by Niall Dickson, chief executive of the NHS Confederation and Sir Hugh Taylor, chair of Guys and St Thomas's NHS Foundation Trust, has held high level meetings with (among others) Jeremy Hunt, the Secretary of State for Health, Lord O'Shaughnessy, Parliamentary Under-Secretary of State for Health, the chair and chief executive of the Medicines and Healthcare Products Regulatory Agency (MHRA) and General Medical Council, the UK Deputy Permanent Representative to the EU (UKRep), and the European Commission's Article 50 Task Force. The alliance has featured in media interviews and press articles.

The alliance has given both written and oral evidence to UK Parliamentary Select Committee enquiries: on reciprocal healthcare, to the House of Lords EU (Home Affairs) Committee; and on medicines, medical devices and substances of human origin, to the House of Commons Health Committee. We have responded to the science and technology inquiry on Brexit science and innovation summit. In addition, we have met with several prominent members of the British and European Parliaments. The BHA was also able to organise and provide a group of experts from the members of the alliance to inform their commissioned work on Brexit and the impact on supply of medicines to the UK.

During phase 1 of the Brexit negotiations in autumn 2017, which focused on citizens' rights, the alliance launched a public campaign on the importance to patients, the public and to healthcare systems of maintaining reciprocal healthcare rights for UK and EU citizens after Brexit. We issued a comprehensive briefing, press statement, blogs, articles and a podcast which received wide media, including social media, coverage.

In order to influence the negotiation priorities for phase 2 negotiations, and the future relationship between the UK and the EU, we have issued two campaigns in the first quarter of 2018.

The second BHA campaign in January 2018 focussed on the impact of Brexit on patient access to medicines and medical technologies. The campaign produced a briefing, with a number of case studies on impact, which was reported in The Guardian, the health trade press, and on BBC Radio 4. The recommendations of the report, and the case studies, have been widely used by UK stakeholders and decision makers and EU stakeholders and partners.

The third BHA campaign on patient access to medical research was published on 28 February 2018, to coincide with Rare Disease Day. The briefing was taken up by both national and Brussels-based press and on social media. This campaign had a specific focus on rare diseases and childhood conditions, and called for UK NHS trusts to continue to be able to lead and participate in European Reference Networks to the benefit of UK and EU patients.

To support the BHA campaign, we worked with Genetic Alliance UK (National Voices member) and

Eurordis (the European organisation for rare disease patients) and the coordinators of all 24 European Reference Networks to ensure aligned messages all going out at the same time.

In her Mansion House speech on 2 March 2018, the Prime Minister reflected the concerns and messaging of our regulation and research campaign, and paved the way to some concessions on the part of the UK government in order to maintain public health. The Labour Party has also reflected the BHA recommendations in their party's red lines on health, so this alignment on our collective BHA messages is a sign of the traction the BHA is gaining within the UK, and the success of the alliance in raising health on the UK negotiating agenda.

The European Commission's negotiating lines for the future relationship with the UK have included recognition of the need to collaborate with the UK on science, some areas of public health and regulatory frameworks, but not all the alliance's concerns have been captured in their lines.

The Cavendish Coalition

Cavendish Coalition
Staffing the health and social care system after Brexit

Following the referendum, a group of organisations from across health and social care, including the NHS Confederation, came together to form the Cavendish Coalition.

The coalition acts as a shared voice which influences and lobbies on the implications of the UK's withdrawal from the EU for the health and social care workforce. It provides expertise and knowledge for those planning and leading the Brexit negotiations, and provides a single point of contact for government, agencies and stakeholders to engage with and understand the workforce issues and opportunities within the sector.

The coalition has three main aims:

- **Seeking certainty for those already working in the UK** by advocating for the right of the current health and social care workforce originating from EEA members to remain in the UK.
- **Promoting employment policy and practice** which ensures that the UK continues to be able to attract people with vital skills from Europe and around the world to work in social care and health.
- **Supporting the economic as well as social health of the communities** we work within, through the creation of opportunities for training and employment.

Throughout 2017, the NHS European Office has played a large part in contributing to the policies and activities of the coalition, including:

- commissioning research from the National Institute for Economic and Social Research analysing the labour market in the health and social care sector and recommending policy options to ensure a future workforce supply for the sector
- providing evidence to the Migration Advisory Committee, which will inform the UK government's future migration policy
- providing evidence to the House of Lords Select Committee on Economic Affairs, on Brexit and the labour market.

"The Cavendish Coalition acts as a shared voice which influences and lobbies on the implications of the UK's withdrawal from the EU for the health and social care workforce."

Monitoring and influencing EU policy and legislation in the interest of the NHS

Changes in data protection law – guidance for the NHS

The use of personal data is at the heart of provision of health and social care. Without the use of personal data, the NHS would not be able to diagnose, treat and care for patients. It is also necessary to use data for research, planning of services and for public health purposes.

NHS chief data officer, Dr Geraint Lewis says:

"In the coming years, the NHS Five Year Forward View is set to revolutionise the way we deliver high quality care for all and data will be at the heart of that transformation. High quality information will empower the health and social care sector in identifying where new care is needed to meet the needs of local populations. Using data, we can determine what care is working well and what needs to be improved, allowing patients, clinicians and commissioners to compare the quality and efficiency of care in different parts of the country."

For this reason, the revision of EU legislation on data protection has been a priority of the NHS European Office since prior to 2012.

As this legislation will be implemented by May 2018, the UK government has confirmed that we will be implementing the new law before Brexit, and we will continue to keep to the legislation, including through the Data Protection Bill.

The NHS European Office consulted data controllers and processors within the NHS extensively during the EU decision-making process to get their detailed views on the points above. We also established strong alliances with UK based stakeholders and pan-European partners to press for a number of changes to be made to the EU proposals.

In particular, we led on the development of a collective national NHS position and made UK negotiating teams and EU decision makers aware of our views and concerns.

In 2016, we moved from a lobbying phase, into a phase of supporting and initialising UK health sector guidance.


Briefing

NHS European Office

Protecting and managing personal data

Changes on the horizon for hospitals and other health and care organisations

Who should read this briefing?

What this briefing is for

Key points

Our office coordinated two initial meetings with the Department of Health, NHS England and other arms length bodies (ALBs) with the UK's supervisory authority, the Information Commissioner's Office, to discuss sector specific application and implementation of some of the provisions of the regulation and the potential need for guidance, training and awareness raising. We produced a briefing which guided the work of ALBs. This work began the process of national sector specific guidance for health and social care organisations.

2017 highlights

Our office played a crucial role in establishing two national working groups on guidance for the NHS (one on health and social care in general, and one on health and social care research specifically). We have supported both groups in the process of drafting a number of pieces of guidance, particularly the *What's new* document, where we also supported the document's design process.

Both working groups have now issued guidance, available at the following websites:

- IGA guidance for health and social care
- HRA guidance for researchers

We have also supported NHS England, through our membership of the European Hospital and Healthcare Federation, to attend an EU expert group (Article 29 working party) which produces European-level guidance. This means that the NHS was able to have a voice in developing guidance which will be critical for the health sector – the most recent being the guidance on transparency.

We attended the European Commission's sector day on health data on behalf of the NHS, and reported back to the working groups.

We have engaged with the European working group which is designing a code of conduct for health data in research. This is essential, particularly in the light of Brexit, as this code may become EU law in the future (through what is known as a delegated act), and it is an opportunity for the NHS to influence the future of this code.

See our data protection webpage for more information.

Changes to medical devices and in vitro diagnostics law – guidance for the NHS

NHS organisations routinely produce diagnostic tests in-house or modify commercial kits to conduct essential specialised tests for specific groups of patients. They also regularly modify or produce medical devices, such as software for MRI scanners and devices for use on special groups of patients (for example, infants and children).

These practices allow the NHS to provide state-of-the-art healthcare to patient groups needing specialised care, to respond rapidly to new or emerging threats, and to promote the development of more innovative solutions through collaboration by medical researchers with their peers. Changes proposed to EU law regulating medical devices were therefore of great importance to us.

2017 highlights

In 2017, we turned our attention to domestic implementation of the two regulations in light of Brexit, to prepare NHS organisations for the changes and to make sense of the extent to which we will have to comply with these new rules in the future.


NHS European Office

Briefing

IPEM

Changes in rules for manufacturing or modifying and use of medical devices including in vitro diagnostic medical devices

Who should read this briefing

What this briefing is for

Key points

To this end, we engaged with the Medicines and Healthcare Products Regulatory Agency (MHRA) implementation team and the Institute of Physics and Engineering in Medicine to produce a briefing on guidance and advice for NHS organisations which coincided with the MHRA's publication of its consultation on the draft health institution exemption.

The briefing will enable NHS organisations to respond to the consultation and also to become early adopters of the new practice. This guidance also puts the legislation in the context of Brexit, and confirms the MHRA is still proceeding with implementing the legislation, even though it will be implemented post Brexit.

See our medical devices webpage for more information.

Implementation of EU law to protect patients from the risk of falsified medicines

Falsified medicines are fake medicines that pass themselves off as real, authorised medicines. They might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose and as such, are a major threat to public health. New EU legislation on falsified medicines was adopted in 2011, introducing tougher rules to improve the protection of public health, with new, harmonised, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled.

Following the adoption of this directive, the European Commission has produced a piece of implementing legislation on safety features for each pack of medicinal products, and the associated authentication process.

2017 highlights

We are now in the phase of preparing for implementation of the new law by 9 February 2019.

Domestically, we have encouraged a flexible approach to implementation as we know many other EU member states are not ready for implementation, and especially in light of Brexit.

We have worked closely with other hospital members of HOPE and have emphasised the complexities of implementation from a hospital perspective, especially when these new measures will create disproportionate costs and administrative burden for hospitals in England, compared to the benefits they will bring in terms of increased patient safety. Currently, there is minimal risk for falsification of drugs in the UK.

Alongside this, to help trusts to positively prepare, we have worked with the UK pilot site for the new system of scanning (Oxford) who have experienced some benefits and have produced papers on what works well and what can be helpful. We have profiled this NHS case study throughout the HOPE network.

Through our lobbying with HOPE, we have secured the opportunity of more possibilities for the use of a list of aggregated codes for scanning, instead of having to scan each pack. This could save hospitals time and logistical problems. This will shortly appear on the Commission's FAQ document.

See our pharmaceuticals webpage for more information.

New proposed EU legislation on Health Technology Assessment

On 31 January 2018, the European Commission proposed a new regulation on Health Technology Assessment (HTA). Although some voluntary joint assessments currently take place between EU member states, the majority are performed at national level, meaning that pharmaceutical companies and medical technology companies often have to carry out a number of parallel assessments for each country. This causes delays in new technologies being taken up in the European market. Because HTAs are conducted to inform decisions on the allocation of budgetary resources, in relation to pricing or whether the cost can be covered by the health service budget, the commission believes that joint HTAs (and a bigger market) can assist member states to equally create and maintain sustainable pricing systems.

The proposed regulation puts forward mandatory joint HTAs for all marketing authorisations applied for through the European Medicines Agency (EMA), and for higher risk medical devices and IVDs. The mandatory nature of these joint assessments will most likely be opposed by a number of EU member states, who will want to maintain the integrity of management of pricing in their own respective health systems.

2017 highlights

Our office has been monitoring the response to this legislation through HOPE and our other EU membership organisations and is preparing to contribute where appropriate to the joint response from these networks.

We will also seek to establish the impact on Brexit of this legislation. If the National Institute for Health and Care Excellence (NICE) is no longer included in the joint assessment work, what impact will that have on the EU's ability to deliver quality HTA? Also, what impact will it have if the EU moves towards joint HTA and the UK/NICE is left out of this system? What would be the impact for NHS and patients in the UK going forward?

Mobility of workers and recognition of professional qualifications

This issue is a matter for the EU's internal market rather than employment law, as it relates to freedom of movement and freedom to provide goods and services. However, health professions are highly mobile, so the ability to have one's qualification recognised, to be able to join the professional register and practise in another country is extremely important to healthcare practitioners, employers and providers of services, and impacts considerably on healthcare systems' workforce planning.

Current EU legislation facilitates movement of healthcare workers across EU borders with a

minimum of bureaucratic obstacles and includes automatic recognition of listed qualifications for doctors, dentists, general care nurses, midwives, and pharmacists. This helps to speed up recruitment and alleviate workforce shortages. It also provides a secure EU-wide alert system for regulators to exchange information about 'rogue' professionals, and lays down minimum education and training standards for recognised qualifications. On the other hand, EU rules can sometimes prevent regulators from applying more stringent standards as these can be seen as obstacles to professional mobility.

Proportionality test

The commission has proposed a directive introducing a requirement for member states to conduct proportionality assessments before introducing new provisions restricting access to or pursuit of regulated professions. This could potentially hinder member states from regulating new healthcare professions or raising the standards regulating existing professions, for example, by strengthening requirements for continuing professional development.

2017 highlights

During 2017, we engaged with the commission and with parliamentarians through our membership of HOSPEEM (European Hospital and Healthcare Employers' Association) to seek to exclude healthcare professions from the scope of the directive on the grounds of patient and public safety, as regulation of healthcare professions is a matter for national, not EU, competence. Our lobbying has been partially successful as the relevant EU Parliament committee has proposed creating a special status for healthcare professions to ensure a high level of public protection.

Carcinogens and mutagens

Cancer is the biggest work-related killer in the EU. Fifty-three per cent of occupational deaths are attributed to cancer caused by exposure to carcinogenic substances. To reduce this toll, EU-wide health and safety legislation on the protection of workers from the risks related to exposure to carcinogens and mutagens at work is being updated, adding new substances to the lists of substances covered by the relevant directive and revising occupational exposure limit values for some of the existing listed substances.

The commission has announced they will propose a new package of amendments which will include setting exposure limits for the medical use of formaldehyde, and discussions have taken place between employers, workers and government representatives at European level to decide the level at which these limits should be set.

2017 highlights

The social partners (employers and trade unions at EU level) have responded to the commission's consultation in 2017 and await the new package of amendments in 2018.

We are liaising with stakeholders in the UK to see whether the resulting proposal will cause any difficulties for the NHS, in particular for pathologists, and if necessary will seek to influence the relevant committees in the European Parliament to ensure a balanced and pragmatic outcome.

"With this new package of amendments, we can better protect millions of EU workers from cancer-causing chemical substances in the work place. This is particularly important given that cancer is the first cause of work-related deaths in the EU"

Facilitating access to EU funds for NHS bodies and their partner organisations

2017 highlights

Since the referendum vote, our office has prioritised providing information to NHS organisations on access to EU funds and how this will be impacted by Brexit.

We have been able to give reassurance on the UK government's commitments to UK organisations wishing to apply for EU research funding.

We have maintained our communication of EU funding opportunities through our relevant bulletins and web pages.

While the UK is still a member of the EU, our office continues to act as the UK's national contact point for EU Health Programme funds. We have communicated results of the programmes, given feedback on the mid-term review of the EU Health Programme, and importantly, we have facilitated access to EU funds for UK NHS ERN coordinators and national agencies working on joint actions.

For more informaion, see our accessing EU funding web page.

Supporting pan-European collaborations and sharing European best practice

We have engaged with a wide range of pan-European organisations representing patients, health sector industries and healthcare providers, to emphasise the mutual benefits to patients across the whole of Europe in maintaining close collaboration in healthcare provision, regulation, research and public health post Brexit.

The work of this group has culminated in pan-European organisations working on health to sign up to a comprehensive statement called *Prioritising patients and public health post Brexit* which was sent to all EU Heath Ministers before the December 2017 EU Health Council.

This 'European health community' also hosted a workshop on Brexit and health in February 2018, which developed a list of key questions and concerns regarding public health and patient safety for both teams in the Brexit negotiations.

The NHS Confederation's membership of two European 'social partner' organisations, HOSPEEM and the European Centre of Employers and Enterprises (CEEP), means we can liaise with our counterparts in other EU countries on matters of mutual concern and respond collectively to the European Commission, who are obliged to consult the social partners on all employment-related legislative proposals. These are valuable channels of influence with the commission and European

Parliament, and will become more so if in future the UK is no longer represented in the EU's decision-making bodies.

The NHS Confederation is the UK member of HOPE. Our membership allows us to work jointly together on pieces of EU legislation which will impact the EU hospital sector. It also is a fantastic forum for sharing expertise and knowledge.

HOPE organises each year study tours for its members, which are circulated to the NHS through our bulletins. The NHS has also hosted these study tours in the past, helping the NHS to profile its work internationally.

HOPE is also a vital source of strategic information and insight on European hospital systems and management. Much of our work programme supporting the NHS vanguards and new models of care came through this network.

Workers' rights: transparent and predictable working conditions

On 21 December 2017, the European Commission adopted a proposal for a new directive for more transparent and predictable working conditions across the EU. It creates new minimum standards to ensure that all workers, including those who are now often excluded such as marginal part-time workers, workers on very short contracts, and on-demand (zero hours) workers, are entitled to information in writing clarifying their working conditions from the start of their employment. It creates new minimum rights such as the right to greater predictability of work for those on a variable schedule, the possibility to request transition to a more stable form of employment and receive a reply in writing, or the right to mandatory training without deduction from salary.

We have exchanged views with our counterparts in CEEP to present a common position to the commission and trade unions.

Next steps

We will follow this legislation closely through the European Parliament and the Council of the European Union, assessing the implications for the NHS and inputting as appropriate through CEEP and HOSPEEM.

Work/life balance

The European Commission has proposed a package of measures aimed at helping parents and carers to better reconcile their work and caring responsibilities, by strengthening existing rights and introducing new ones. The proposals include greater protection for women from dismissal related to maternity; right to ten days' paternity leave; parental leave of four months for both parents, with the possibility of flexible (for example, part-time) uptake; five days' carer's leave per annum; and the rights for parents of children under 12 to request flexible working arrangements. Leave should be paid at least at sick pay level.

Our office has contributed to the social partner responses in 2017 to the commission's consultations on work/life balance, stressing the need for proposals to be sensitive to the very different legislative and contractual provisions in different member states and to respect the principle of subsidiarity. We have followed the passage of this legislation closely so far to assess its likely impact on the NHS, which will depend on how the final EU rules compare with current NHS contractual terms and conditions.

Next steps

These proposals will continue to be extensively debated and possibly amended in the European Parliament and Council during 2018, and we anticipate there will be considerable opportunity to influence the final outcome at EU level.

Collaboration at European level on occupational health: musculo-skeletal problems, stress, and sharps injuries

Through our membership of HOSPEEM, the NHS European Office has been involved throughout 2017 in joint working between HOSPEEM and the European Federation of Public Service Unions (EPSU) on projects to share and disseminate good practice in the field of occupational health. Successful conferences were held on the topics of tackling musculo-skeletal problems and stress at work, bringing together health sector employers and trade unions from across the EU.

We contributed to these events by inviting speakers from NHS employers and trade unions to share with our European counterparts case studies of joint working resulting in the toolkits on back care and health and wellbeing. This work will continue with a further event in May 2018 on promoting good mental health at work.

Several years ago, HOSPEEM and EPSU negotiated an agreement which resulted in Directive 2010/32/EU on the prevention of sharps injuries (such as needlestick injuries) for healthcare workers. They are now collecting feedback from their members investigating how effectively this has been implemented and whether further follow-up action, if any, is needed. The results will be shared with the European Commission and other relevant stakeholders (such as the European Occupational Safety and Health Agency, EU OSHA).

Finally, it is now ten years since employers and unions at EU level agreed a code of conduct on ethical cross-border recruitment and retention of healthcare workers. We will be reviewing its impact and sharing experiences across member states of the benefits and disadvantages of healthcare worker mobility, the impact on workforce planning and staff shortages, and lessons learnt about good (and bad) practice.

"The proposals will continue to be extensively debated during 2018 and we anticipate there will be considerable opportunity to influence the final outcome at EU level."

The NHS European Office

The impact of the EU agenda on the NHS is constantly increasing, bringing with it both challenges and opportunities. The NHS European Office is the conduit for the NHS to engage with the EU agenda. Hosted by the NHS Confederation, we are the representative body for the range of NHS organisations in England on EU affairs. Our work includes:

- making sense of how the UK exiting the EU may impact on NHS organisations and ensuring that decision makers are aware of the impact on the health sector and patients.
- facilitating access to EU funds for NHS bodies and their partner organisations
- supporting pan-European collaborations and sharing successful EU practices.

For more information on EU affairs of importance to the NHS and to get in touch with the NHS European Office, visit www.nhsconfed.org/europe or email european.office@nhsconfed.org

NHS European Office

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