This update includes information on the forthcoming HPCB meeting on the professional qualifications Directive; the European Commission’s proposal to amend Directive 2005/36/EC; and the European regulators’ meetings of midwives and doctors. It also features articles on recent European Court of Justice and European Free Trade Association court rulings; the removal of the three year UK rule for EU qualified pharmacists; and plans from the UK General Dental Council to develop revalidation.

HPCB meeting on recognition Directive


Hosted by Emma McClarkin MEP and Antonia Parvanova MEP, the event entitled ‘The new recognition of professional qualifications Directive: what’s at stake for patient safety?’ will provide an opportunity for healthcare professional regulators to discuss the European Commission’s (EC) proposal to amend Directive 2005/36/EC. The programme will consider key issues including:

- the European professional card;
- language requirements;
- the IMI alert mechanism; and
- education & training for healthcare professionals.

Speakers include representatives from the Internal Market and Consumer Protection committee (IMCO), the European Commission, the Danish Presidency (tbc), MEPs and senior colleagues from healthcare professional regulators and patient safety organisations.

The meeting is open to competent authorities responsible for the implementation of the recognition Directive and patients and consumer groups in the European Economic Area (EEA). For further information, please contact the HPCB Secretariat.
The modernisation of the Directive is one of the twelve key priorities outlined in the Single Market Act.

On the day of the launch, Internal Market Commissioner Michel Barnier said that the proposal will ‘make it easier for well qualified professionals to go where job vacancies exist. And this will certainly prove beneficial for the growth of the European economy.’

New areas covered by the revised Directive include the introduction of an alert mechanism, the mandatory use of the Internal Market Information System (IMI), an IMI e-certificate (also known as the ‘professional card’) and new recognition deadlines.

The language proposals in the Directive have also been revised. It remains unclear whether competent authorities responsible for healthcare professionals would be allowed to satisfy themselves of language proficiency before registration. During the consultation period on the 2005/36/EC Directive regulators called for clear exemptions from the language provisions in the Directive on patient safety grounds.

The text also gives the EC responsibility, through delegated acts, to update the minimum training requirements for doctors, dentists, pharmacists, nurses and midwives.

The EP’s IMCO committee will lead on the proposal in the European Parliament (EP) and has recently published its timetable for the Directive.

Bernadette Vergnaud, a French MEP for the Progressive Alliance of Socialists & Democrats (S&D) group has been confirmed as the IMCO rapporteur for the proposal. She is expected to draft her report on the proposal by July and a first reading vote in plenary is provisionally scheduled for January 2013.

European Network of Medical Competent Authorities responds to Commission proposal

At the 6th meeting of the European Network of Medical Competent Authorities (ENMCA) held in Rome on 23 January 2012 and hosted by the Italian Ministry of Health, participants agreed a joint position on the EC proposal to modernise the 2005/36/EC Directive.

Forty delegates across Europe attended the meeting and considered in detail the proposals in the draft legislative text in the presence of Jürgen Tiedje, Head of Professional Qualifications at the European Commission’s Internal Market Directorate-General.

The meeting led to the agreement of an ENMCA position on the proposal to reform the Directive which states that:

- host member states should remain responsible for the recognition of professional qualifications;
- the concept of tacit authorisation should be removed from the Directive proposal;
- the proposed recognition deadlines are too ambitious and should be agreed instead in the context of pilot projects that will improve the IMI system in conjunction with an e-certificate;
- the language requirements in the Directive require further clarification;
- the involvement of competent authorities in delegated and implementing acts envisaged for the implementation of the e-certificate, the IMI alert mechanism and the modernisation of minimum training requirements, should be enshrined in the Directive.

To date, the ENMCA statement has been endorsed by 24 competent authorities across Europe and will form the basis of future Network engagement with EU decision-makers in the coming months.

To view ENMCA’s response to the European Commission proposal to modernise the 2005/26/EC Directive, please click here.
Following the publication of the EC’s proposal to modernise the professional qualifications Directive, the Network of European Midwifery Regulators (NEMIR) is considering a joint paper on the proposal. A meeting of the policy working group is planned in March 2012, and the NEMIR annual summit will take place in May 2012.

There is likely to be some debate among the Network’s midwifery regulators on the proposal to update the minimum training requirements in the Directive and annex V. The latter will be revised by means of delegated acts.

The EC says in the recitals of the proposal: ‘The nursing and midwifery professions have significantly evolved in the last three decades: community-based healthcare, the use of more complex therapies and constantly developing technology presuppose a capacity for higher responsibilities for nurses and midwives.’ It has chosen to upgrade the general school education requirements for midwives by requiring ‘completion of at least the 12 years of general school education or a certificate attesting success in an examination, of an equivalent level, for admission to a midwifery school for route I’. The same requirements are proposed for access to the nursing profession.

According to the Commission, this upgrade is justified by the complex healthcare needs that midwives have to serve. The Network is likely to call for the same approach to apply to the development of competencies and initial training requirements. It will also ask the European Commission to give competent authorities guarantees that they will be involved in the delegated acts which will be required to update the training requirements.

Upgrading midwifery training requirements
Charlotte Creiser, Conseil National de l’Ordre des Sages-femmes

European Court Updates

ECJ opinion on temporary and occasional

In September 2011, an employment tribunal for healthcare professionals in Gießen, Germany, referred a case (C-475/11) involving a doctor practising under the temporary and occasional provisions of Directive 2005/36/EC to the ECJ for a preliminary ruling.

The doctor challenged the tribunal’s decision to take action against him under the state medical code of conduct (Berufsoordnung für die Ärztinnen und Ärzte in Hessen) for unprofessional advertising on the basis that, under temporary and occasional mobility, he was not required to pay a registration fee and as such the code would not apply to him.

The tribunal is now seeking an opinion from the ECJ on whether its decision to take action against the doctor is compatible with Directive 2005/36/EC and if the relevant codes of conduct and provisions concerning professional disciplinary tribunals are applicable to professionals working temporarily in the host member state.

EFTA court opinion – language assessment

In December 2011, the European Free Trade Association (EFTA) court gave its opinion on a case concerning a decision by the Norwegian Appeal Board for Health Personnel to deny full registration to a Bulgarian doctor on the basis of their language skills.

The court found that competent authorities may make registration to practise medicine conditional upon the applicant having the necessary language skills, given that a doctor’s ability to communicate with colleagues and patients constitutes a general public interest.

The opinion outlined that competent authorities are not normally allowed to make a discretionary assessment of a professional’s language or competence, given the harmonised minimum training requirements outlined in the Directive. However, the Court took the view that in exceptional circumstances, competent authorities must be able to deny full authorisation to professionals if there are overriding reasons of public protection, and upheld the decision by the Norwegian Appeal Board.
UK removes three year rule for EU qualified pharmacists

Martha Pawluczyk, Registrations Manager, General Pharmaceutical Council

EU-qualified pharmacists can now be in charge of a newly established pharmacy.

Previously known as the ‘three year rule’, pharmacists who registered with the UK General Pharmaceutical Council (GPhC) with a qualification from the EEA and Switzerland, were unable to work as the responsible pharmacist in pharmacies in Great Britain that had been registered with the GPhC for less than three years, according to a derogation allowed under Directive 2005/36/EC.

Following a change in UK law, EU qualified pharmacists can now be in charge of any registered pharmacy in the UK. The change also allows ‘visiting pharmacists’ to be the responsible pharmacist in any registered pharmacy.

Pharmacies in Great Britain are registered with the GPhC and pharmacies in Northern Ireland are registered with the Pharmaceutical Society of Northern Ireland (PSNI).

GMC review of the PLAB test

Neil Jinks, Senior Policy Analyst, Registration and Resources, General Medical Council

The General Medical Council’s (GMC) Professional Linguistic and Assessments Board (PLAB) test is the main route through which doctors who qualified outside the EEA demonstrate their clinical knowledge and skills before joining the UK register.

The GMC regularly reviews the PLAB test to make sure that it continues to be fair, robust and follows best practice. The latest review is now underway and is being overseen by an independently led working group. The working group brings a range of perspectives to the review, including patients, medical educators, employers and overseas-trained doctors. It will report to the GMC’s Council, with recommendations, in early 2013.

The review’s terms of reference focus on four broad themes: standards; the content of the test; its reliability and validity; and work-place and educational outcomes for international medical graduates who have passed the PLAB test.

The working group would like to hear the views of a wide range of interested parties on various aspects of the PLAB test to inform the review. The GMC has therefore issued a call for written evidence and will also invite a range of respondents to give oral evidence, once written submissions have been gathered.

Alongside this, the working group will consider a literature review focused on best practice in examination and assessment methodologies and a primary research project on work-place and educational outcomes.

The working group would like to hear what other regulatory and licensing bodies, in the UK or overseas, think about the PLAB test, and learn from any comparable arrangements in other jurisdictions for overseas qualified professionals.

We encourage overseas regulators to contribute to our review by responding to our call for written evidence by 30 April 2012.
Raising Concerns: UK regulators issue guidance

In the UK, the inquiry into events at the mid-Staffordshire hospitals and a recent UK parliamentary report have highlighted the importance of practitioners’ full understanding of the professional standards expected of them. This has led to a focus on the need to encourage and support health professionals to report concerns about the quality of care being delivered by their colleagues.

UK regulators have been working to improve registrants’ understanding of their responsibilities in this area. In November 2011, the GPhC consulted on draft guidance on Raising Concerns. The text reminds practitioners of the action they must take to protect the well-being of patients and the public and provides advice on the steps involved in raising a concern.

In January 2012, the GMC published new guidance Raising and acting on concerns about patient safety which makes clear that doctors must not sign contracts that attempt to prevent them from raising concerns with professional regulators. The guidance explains when doctors need to raise concerns and advises on the help and support available to them, including how to tackle any barriers that they may face.

The UK Care Quality Commission, which is the independent regulator of all health and social care services in England, also published Whistleblowing: a quick guide to raising a concern about your workplace in December 2011.

General Dental Council working to develop revalidation

Claire Herbert, Head of Revalidation, General Dental Council

The General Dental Council (GDC) regulates all dentists and Dental Care Professionals (DCPs) that practise in the United Kingdom. Like the other UK professional healthcare regulators we are working to develop revalidation. This is a way of enabling our registrants to regularly demonstrate to us, and patients and the public, that they are keeping up to date and practising in accordance with our Standards for Dental Professionals.

A key part of our approach to revalidation will be ensuring that GDC registrants keep their knowledge and skills up to date through continuing professional development (CPD). This is activity such as courses, reading or private study. The GDC already makes it mandatory for registrants to participate in CPD and all our registrants must undertake a minimum number of CPD hours every 5 years to maintain their registration.

Alongside developing revalidation, in July 2011, we launched a review of our current CPD scheme to make sure it continues to effectively contribute to helping dentists and DCPs practising in the UK keep up to date. The review will take a couple of years and enable us to look in depth at on-going learning and development in dentistry, what makes it effective and how we can support registrants to get the most out of it.

As part of this, we have commissioned some research projects to look in more detail at the role and impact of CPD in dental regulation. In November 2011, we published a literature review entitled The Impact of Continuing Professional Development in Dentistry. The research team was led by Professor Kenneth Eaton, who is also an adviser to European chief dental officers. The study is one of the first of its kind focusing on the regulatory benefits of CPD in dentistry and is now available on our website. We have also undertaken a representative survey of our registrants to find out how they do CPD and how they think it benefits their practice. With a 34% response rate, many dentists and DCPs were keen to share their views with us, and the findings are due to be published shortly.

The GDC believes that participation in CPD is invaluable to keeping dental skills and knowledge up to date and maintaining quality of care in dentistry. Our CPD scheme to date has played a key role in further embedding on-going learning and development into UK dentistry. We encourage similar developments across the EEA and would like to see all competent authorities in the EEA develop systems for monitoring compliance with CPD.

We will continue to review CPD for dentists and DCPs throughout 2012, and would be willing to share ideas and experiences on CPD with fellow regulators from across Europe. We would also be keen to hear more about how other regulators approach CPD, particularly in the context of the current proposals to revise the recognition of professional qualifications Directive. For more information please see the GDC website or contact Claire Herbert, Head of Revalidation at: cherbert@gdc-uk.org.
The GMC is continuing its programme of work to develop a new edition of its core guidance for doctors, *Good Medical Practice* (GMP). The guidance sets out the values and principles on which good medical practice is founded and all doctors need to follow it.

GMP plays an important role in the functions of the GMC. It provides:
- the foundation for appraisal and revalidation;
- informs the medical undergraduate and postgraduate curricula;
- is used in assessing doctors’ fitness to practise.

We launched a consultation on a revised version of GMP at the end of October 2011. This closed on 10 February 2012. It was important to hear from as many sources as possible about the guidance, to make sure it remains relevant for all doctors working today and reflects patients’ views of good practice.

As part of this programme of work, we are also going to review and develop the guidance that supports GMP including: doctors acting as witnesses; working with colleagues; maintaining boundaries and ending professional relationships with patients. If you would like to take part in this further consultation to be held in Spring 2012, please let us know.

For more information you can read about the review and keep up to date on the GMP 2012 website or contact the Standards & Ethics Team at: standards@gmc-uk.org.

The GMC has launched *Your Health Matters*, a new website for doctors who may be concerned about their own health or that of a colleague. It provides case studies showing doctors with a range of health concerns, a testimonial from a doctor who has gone through our fitness to practise procedures, and a range of advice on the process.

The GMC recognises the distress experienced by many doctors whose health has affected their ability to practise and understands fitness to practise procedures can bring additional stress. While the GMC must never compromise on standards of patient safety, it is important to support doctors with health problems and help them back to safe practice wherever possible. The website has been developed with input from the Doctors’ Support Network, the British Medical Association and support from the Practitioner Health Programme.

The Irish Medical Times reports that the Republic of Ireland’s government has advised the EC that it plans to comply with the European Working Time Directive (EWTD) rules within a three year timeframe. It will implement new working patterns for staff; transfer work undertaken by non-consultation hospital doctors (NCHDs) to other grades; and reorganise hospital services. The Irish government noted that difficulty in recruiting doctors for NCHD posts had undermined efforts to achieve full compliance.
**Around the world**

**HPSCA investigates fraudulent doctor**

The Health Professions Council of South Africa (HPSCA) has announced an investigation into its registration procedures after it emerged that a Congolese doctor, Nyunyi Katumba, was fraudulently working as a neurosurgeon in the country. Mr Katumba produced false evidence to the Council claiming to have passed specialist exams, which he had failed and has now been removed from the register. HPSCA President, Sam Mokgokong advised that the Council is working to tighten its procedures and that two employees are currently under investigation. Once the internal inquiry is complete a criminal charge is likely to be laid against Mr Katumba. The HPCSA are currently undertaking a review of registration files.

**Malaysian Medical Council set to become an independent body**

The Malaysian government has announced its decision to amend the Medical Act to give greater independence to the Malaysian Medical Council. It will now be responsible for maintaining medical standards in the country and performance monitoring of doctors. The authorities hope that an independent professional body with a greater remit will address concerns over declining medical standards.

---

**Upcoming dates and events**

- **7 March 2012**
  HPCB 2012 Conference
  Brussels, Belgium

- **26 – 27 April 2012**
  Bologna Ministerial Meeting
  Bucharest, Hungary

- **April/May 2012 (tbc)**
  European Network of Medical Competent Authorities meeting

- **May 2012 (tbc)**
  Network of European Midwifery Regulators summit

- **1 June 2012**
  European Council of Medical Orders meeting
  Ljubjana, Slovenia

- **2 – 5 October 2012**
  International Association of Medical Regulatory Authorities Conference
  Ottawa, Canada

---

**Recently published regulators’ newsletters**

- Eurohealth
- French Order of Doctors
- GDC update
- GMC Education update
- GMC Student news
- GMC News
- HPC News
- IAMRA newsletter
- NMC Review
Agreement 1
Identifying Shared Principles of Regulation:

a) Competent authorities should ensure that patient safety is of over-riding importance within their model of professional regulation.

b) The pursuit of safe and high quality practice by health professionals should shape the continued development of health regulation across Europe.

c) Competent authorities should identify common or shared concepts and values of healthcare regulation through a series of focused European level discussions.

d) Competent authorities should collectively consider how the five principles of good regulation – accountability, transparency, proportionality, consistency, targeting – may contribute to the effective development of healthcare regulation in Europe, through a series of European level discussions.

Agreement 2
Transparent and Accessible Healthcare Regulation:

a) Competent authorities should run a website signposted or accessible via the www.healthregulation.org website and/or http://ec.europa.eu/internal_market/qualifications/compauth_en.htm.

b) Competent authorities will share experience in the development of web-based information and publicly transparent lists of registered professionals and identify good practice.

c) Competent authorities should work to develop real-time web-based publicly searchable lists of registered professionals.

d) Competent authorities should work towards making all notifications of disciplinary hearings and decisions public, where legally possible.

e) Competent authorities will continue to adopt and implement the European template for a Certificate of Current Professional Status, as appropriate, as agreed within the Edinburgh Agreement.

f) Competent authorities will continue to work towards adopting the HPCB Memorandum of Understanding on Case by Case and Proactive information exchange.

g) Competent authorities will continue to support the development of the European Commission’s Internal Market Information System (IMI) and will utilise this information exchange tool in accordance with the provisions for administrative cooperation contained within Directive 2005/36/EC.

Agreement 3
Competence Assurance of European Healthcare Professionals:

a) Competent authorities will identify best practice from existing competence assurance and performance enhancement initiatives from across the globe.

b) Competent authorities will undertake an audit of all existing or proposed competence assurance and performance enhancement initiatives within the EEA.

c) Competent authorities should, where possible, work to develop appropriate competence assurance and performance enhancement initiatives based on global good practice.

d) Competent authorities should develop appropriate information exchange tools to provide assurance to other competent authorities of current practitioner performance competence when practitioners seek to practise in other member states.

e) All competent authorities should take proactive steps to make new registrants familiar with the relevant professional standards, codes and guidance on registration that apply in their jurisdiction.

f) All competent authorities should make their standards, codes and guidance publicly available.