

## Crossing Borders Update



Welcome to the summer edition of the Healthcare Professionals Crossing Borders (HPCB) Update. In this edition we look at the European Commission's analysis of the European professional card and alert mechanism. We also hear from the British Medical Association (BMA) on its *Keeping Europe Healthy* event, and from the new Joint Tender entitled *Support for the hEalth workforce planning and forecasting Expert Network (SEPEN)* led by the Semmelweis University in Hungary. FEDCAR, CPME/CED and PGEU have also provided us with their views on the new Proportionality Test Directive. Finally, we pleased to announce that the next HPCB conference will be held on 4 February 2019 in Dublin, Ireland. More details of the event can be found on page 3.

### EC analysis of the European professional card and alert mechanism

The European Commission [has published an assessment of stakeholders' experience](#) of the European professional card and alert mechanism. The two tools were introduced in January 2016 as part of the revised Directive on the mutual recognition of professional qualifications.

The European professional card (EPC) is a way for professionals to have their qualifications recognised in another EU country. The system is currently available for the following five professions: mountain guides, pharmacists, physiotherapists, nurses responsible for general care and real estate agents.

To ensure that EU patients are adequately

protected, an alert mechanism was also introduced in parallel with the EPC. EU member states are required to use this mechanism to quickly warn each other about rogue professionals. Both tools work via the Internal Market Information system (IMI), an IT application used to connect public authorities across the EU.

The staff working document, published in April, builds on feedback the Commission received in several expert meetings, through a conference where the [HPCB presented its recommendations, a workshop](#), bilateral exchanges with member states authorities, as well as a [public survey](#).

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According to the report, a total of 3,997 EPC applications were submitted during the period between 18 January 2016 and 30 November 2017. The EPC statistics show that physiotherapists were the most active in the period - they represent 38% of all applications with 1,529 applications. Physiotherapists were followed by nurses responsible for general care with a share of 26% (1,037) of the total applications. They were followed by mountain guides (23%, 903 applications), pharmacists (10%, 396 applications), and real estate agents (3%, 132 applications).

A total of 13,597 alerts were sent by the member state authorities in the period between the introduction of the alert mechanism on 18 January 2016 and 30 November 2017. The vast majority of the alerts were for cases where a professional was restricted or prohibited from practice.

Only five alerts were for the use of falsified diplomas.

The EC has stated that statistical analysis and stakeholder feedback have also confirmed that the IMI system is the right platform for these initiatives and the report underlines the importance of continuous fine-tuning of the platform's functionalities. A number of improvements have been made to improve the system for both the EPC and alert mechanism throughout the implementation period.

The report does not make any proposals to extend the European professional card to other professions and the EC intends to improve the existing legal and technical guidance to ensure that the two tools can respond to the needs of professionals and patients.

## HPCB recommendations on the EPC and alert mechanism

Following the HPCB conference and launch of our sanctions mapping exercise in October 2016 the HPCB issued recommendations to the European Commission on the EPC and alert mechanism. These can be found below. In their assessment of the EPC the Commission has taken some of recommendations on board and have planned further improvements to the EPC.



### Alert mechanism recommendations

- 1** **Functionality to update an alert once broadcast**
  - a Improve the functionality of the alert mechanism by introducing the ability to make updates to existing alerts. This will reduce the overall number of alerts being sent and help to address some of the concerns regarding resource burden associated with the high numbers of alerts received.
- 2** **Functionality for requesting and providing additional information via IMI**
  - a Develop guidance and standards to advise authorities in what circumstances authorities can ask for further information
  - b Publish best practise guidance for responding to requests for further information about an alert
  - c Review the set of questions in IMI and draft guidance to support the requesting of further information
  - d Introduce a free text box for prohibitions.
- 3** **Inconsistent use of the IMI system**
  - a Convene a small group of competent authorities to draw up guidance for all competent authorities on the use of the alert mechanism
  - b Consider amending the alert interface to make clear upfront whether the alert is being sent for a non-substantive reason including drop down options (i.e. non-payment of fees) so that a receiving country can quickly establish how to process each alert.
- 4** **Linking IMI up with national systems**
  - a Prioritise IT interoperability between national systems and IMI to ease the burden on competent authorities.
- 5** **Pre-dating the alert mechanism**
  - a Consider whether it would be operationally feasible to add sanctions issued prior to January 2016 to the IMI system.

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## European professional care (EPC) recommendations

- 1 **Administrative burden on home member state**
  - a Revisit the responsibilities of the home and host member state to ensure that host countries are not overburdened by the need to verify large numbers of documents, and that host member states are able to assure themselves of the validity and content of documents.
- 2 **Duplication of existing methods of recognition**
  - a Improve the clarity of the EPC website to highlight that the EPC does not grant access to the profession and that the usual national registration rules must still be met.
- 3 **High numbers of failure rates**
  - a Improve the information available for applicants on the EPC interface
  - b Consider whether it is appropriate for applicants to select their route to recognition when these are governed by strict legal rules and may not be easily understood.
- 4 **Temporary & occasional registration applications**
  - a Amend the EPC process so that in cases of temporary & occasional applications without prior check of qualifications (i.e. for sectoral professions), the host member state is able to view the full details of application as soon as it is made so as to enable it to assess whether the automatic route is appropriate and the application is genuinely temporary & occasional to allow it to revoke the EPC if necessary and in a timely manner.

## EC confirms future of RPQ post Brexit

The European Commission has published the latest in its series of [notices to stakeholders](#) advising on the impact of EU exit to specific policies. This notice concerns the recognition of professional qualifications and confirms that:

- The withdrawal of the United Kingdom does not affect decisions on the recognition of professional qualifications obtained in the United Kingdom taken before the withdrawal date on the basis of Directive 2005/36/EC by an EU-27 member state.
- As of the withdrawal date, United Kingdom nationals will be third country nationals and hence Directive 2005/36/EC no longer applies to them. If they apply for recognition in an EU member state, it will be under their national process for assessing the qualifications of international medical graduates

- Qualifications obtained in the United Kingdom by EU nationals (other than UK nationals) as of the withdrawal date will be classed as third country qualifications for the purpose of EU law. Recognition of such a qualification will no longer be covered by the recognition regime of Directive 2005/36/EC

The notices advises EU nationals holding UK professional qualifications obtained before the withdrawal date to consider whether it is advisable to obtain, before the withdrawal date, the recognition of those UK professional qualifications in an EU-27 member state. The above rules will come into force either on 29 March 2019 if there is no Withdrawal Agreement, or at the end of the transition period if one is agreed.

## Save the date – 2019 HPCB conference

We are pleased to announce that the next Healthcare Professionals Crossing Borders conference, jointly hosted by the Health and Social Care Professionals Council (CORU) and the Pharmaceutical Society of Ireland will be on **Monday 4 February 2019** at Dublin Castle, Ireland.

The conference will focus on issues such as Brexit and updates on what is happening in Europe in relation to the movement of health and social care professionals.

Further details can be found on the [HPCB website](#) and the upcoming editions of the HPCB update.



## “SEPEN” Joint Tender in the field of European health workforce planning



SUPPORT FOR THE HEALTH  
WORKFORCE PLANNING AND  
FORECASTING EXPERT NETWORK

### What is “SEPEN”?

The [Support for the hEalth workforce Planning and forecasting Expert Network \(SEPEN\)](#) joint tender is a new action in the field of European health workforce planning. The action supported by the health programme of the European Union and is to establish an expert network on health workforce planning and forecasting.

Led by the Semmelweis University in Hungary, SEPEN brings together partners from the University of Leuven (KUL), the Italian National Agency for Regional Health Services (Agenas), the Italian Ministry of Health (MDS), and the Standing Committee of European Doctors (CPME). The three-year long tender was launched in September 2017 and is funded by the 3rd Health Programme of the European Union (2014-2020).

As an important driver of the health workforce planning agenda, the key objective of SEPEN is to support and strengthen the cooperation of experts working in related fields. SEPEN aims to create and proactively manage a living network capturing international, national and regional views on health workforce planning and aims to provide a dynamic platform for policy dialogues, event announcements, research activities, or sharing expertise and newly published materials.

### A brand new European platform for health workforce planning experts

SEPEN is implementing and activating a health workforce planning and forecasting expert network and, at the same time, intends to identify and solve real-life problems in workforce planning processes, by bringing experts together with those who are seeking to build expertise. Joining the network will provide a forum for experts to exchange ideas and share best practice. It will work alongside [The EU Health Policy Platform](#) (EU HPP) which serves as an online platform for discussions between health workforce experts.

A designated group on the EU HPP was recently launched and registrations are warmly welcome. Registration to the SEPEN expert network is possible via [this link](#).

### News and events

To share the most up-to-date information SEPEN has started to publish a quarterly “EU Health Workforce Network Update” [newsletter](#) and regularly publishes up-to-date news and activities on its official [website](#).

The Joint Tender will organise workshops to bring together countries with similar health workforce characteristics or health workforce planning needs to “maximise the added value of the knowledge sharing across Europe”. The first workshop of SEPEN, held in Brussels in February 2018, was dedicated to the topic of health workforce planning in relation to health professionals’ skills. The video of the keynote speeches is available via [this link](#).

Further workshops will focus on various aspects of health workforce planning (e.g. data and mobility). At the workshops, participants will have the opportunity to reflect on the health workforce challenges they currently face, exchange best practices and improve health workforce planning. You can [sign-up to SEPEN’s next workshop here](#).

### Tailored interventions

As part of the tender activities SEPEN aims to sustain cross-country cooperation and provide support to member states to increase their knowledge, improve their tools and succeed in achieving a higher effectiveness in health workforce planning processes and policy. A call for interest was launched to govern the attention of EU member states to take the opportunity to receive tailored advice and guidance from experts in their national or sub-national level. Applications are still open for member states [here](#). Selected member states will benefit from a national exchange of expertise, such as workshops, training/coaching and peer reviewing.

For more information, please see the official website of the “SEPEN” Joint Tender: [healthworkforce.eu](http://healthworkforce.eu).

## Study on cross-border cooperation

The European Commission has released a [Study on Cross-Border Cooperation: Capitalising on existing initiatives for cooperation in cross-border regions](#). The study investigates past achievements and potential future developments in the field of cross-border healthcare collaboration. The findings are based on a mapping of EU-funded cross-border healthcare initiatives, foresight modelling for cross-border healthcare in 2030, a systematic literature review on fraud and fraud mitigation in cross-border healthcare and an evaluation of take-up of the Joint Action on Patient Safety and Quality of Care (PaSQ).

The study enhances an in-depth understanding of cross-border healthcare collaborations and provides new knowledge to the field on different aspects of cross-border healthcare research. Seven lessons were highlighted by the report and are summarised below:

- 1 Cross-border healthcare initiatives are more effective in regions where ease of cooperation is already established, e.g. due to similar welfare traditions or close historical ties
- 2 Support should be given to key players such as regional policymakers or hospital managers to reduce transaction costs of cross-border healthcare. The toolbox developed in this study can provide help
- 3 There are several scenarios for future cross-border healthcare, one of the most realistic being one which builds regional networks oriented towards addressing local and regional needs
- 4 Regional networks are likely to represent a low-cost option, but the downsides are that they are likely to remain small-scale and they may create inequities by not benefitting all regions equally

- 5 Top categories of cross-border healthcare initiatives to receive EU funding over the past 10 years are: knowledge sharing and management; and shared treatment and diagnosis of patients
- 6 Collaborations such as high cost capital investments and emergency care tend to have more discernible economic and social benefits, but require more formalised terms of cooperation
- 7 Although information on the effectiveness and sustainability of current cross-border healthcare initiatives is scarce, funding of the cross-border healthcare projects could help achieve this.



## Patients' rights in the European Union: final report

The European Commission's DG SANTE has released a report that aims to provide an overview of patients' rights in all EU member states, Norway and Iceland by mapping national patients' rights legislation, soft-law, structures and enforcement procedures ensuring the rights of patients.

The mapping exercise was performed from January to September 2015 providing a cross-sectoral view of the patients' rights situation in the 30 countries in the study.

## Professional qualification: Commission requests France to change its practices

The European Commission has sent a reasoned opinion to France requesting it to change the way it qualifies psychomotor therapists trained in Belgium. French authorities refuse to recognise such qualifications on the grounds that in Belgium, contrary to France, the profession is not classified as a health profession. According to EU rules on recognition of professional qualifications ([Directive 2005/36/EC](#)), foreign qualifications should be assessed based on the activities effectively performed in the home member state.

In the Commission's view, the French practice does not respect this Directive. France now has two months to notify the Commission of the measures taken to comply with the Directive; otherwise the Commission may decide to refer it to the Court of Justice of the EU.

## Proportionality Directive

MEPs and member states have reached agreement on the final wording of [the new Proportionality Test Directive](#) which commits member states to undertaking proportionality assessments before the introduction of new regulatory rules. Under the final agreement, health professions will be covered by the new Directive although the text recognises the special nature of health professions and gives authorities discretion to ensure that a high level of health protection is respected when regulating such professions.

The Directive will be formally adopted over the summer and is likely to be implemented by 2020.

Below we hear from Cédric Grolleau from the Federation of European Dental Competent Authorities (FEDCAR), regarding their views on the Proportionality Test Directive. We also publish a joint press release from the CPME, CED and PGEU on the final compromise of the Directive.

## The Proportionality Test Directive and the Unexpected Effective Remedy

### *Cédric Grolleau, FEDCAR*

The dialogue between health professions and EU institutions on mandating a proportionality test before the regulation of new professions has resulted in the final version of the Directive introducing limits to the proportionality test in healthcare. These changes now reflect European case law. FEDCAR welcomes the changes, which will apply from the end of 2020 for new regulated professions - time will tell whether these changes will be sufficient.

During the Directive's negotiations, the legislator accepted an amendment tabled by MEPs obliging member states to ensure that 'an effective remedy is available with regards to the matters covered by this Directive in accordance with procedures, laid down in national law' (Article 9). This changes the original nature of the Directive and the scope of the proportionality test.

### **Changes to the original nature of the Directive**

The first version of the Directive only obliged member states to notify the European Commission of the outcome of its proportionality tests – as a formality. However, under the revised Directive, future proportionality tests on future professional regulation may be subject to court challenge at a national level. According to the very general wording

of Article 9, it will be possible to challenge the outcome of a proportionality test in the national courts on two grounds: an infringement on procedure (for example, on the independence of the evaluation or on the scope of consultation exercise) and an infringement of principle (for example, on the 'proportionality' of the new regulation).

### **Changes to the scope of the proportionality test**

Until now, decisions concerning the proportionality of regulation have been the responsibility of the European Court of Justice. The Directive will decentralise this. From 2020, the decisions on proportionality tests will be subject to national judicial oversight.

Currently, one can contest a national provision limiting access to, or the exercise of, a profession (for example, limits on professional advertising or on access to capital) and claim it does not comply with the Treaty's rights concerning the provision of services or on free establishment. Most of the time, a preliminary ruling at national level is referred to the EU Court and in the best situation the case is decided within one year. The Directive simplifies this.

From 2020, private parties do not have to claim that a regulation breaches the terms of the Treaty, and instead can ask domestic judges to assess whether the new professional

regulation properly deals with the 'the matters covered by this Directive', including the criteria (about 20 criteria) that should be used for the proportionality assessment. The ability to challenge new regulations will be made easier under the new Directive.

In the original version of the text, the Commission agreed that the Directive would control and monitor the proportionality of the almost 6,000 existing national regulations in Europe and in the Directive's final version, the Commission now has an ally - the litigant.

## European dentists, pharmacists and doctors welcome the final compromise on the Proportionality Directive



### Joint statement from the CPME, CED and PGEU

European dentists, pharmacists and doctors welcome the outcome of the negotiations on the proposal for a Directive on a proportionality test as a better balance between the need to safeguard health and the economic objectives of the Directive than the Commission proposal. While not fully addressing our concerns, the final text recognises the special nature of health professions and ensures a sufficient margin of discretion to member states to guarantee the highest level of human health protection when regulating health professions.

As CED President Dr Marco Landi states "I welcome the decision to refer to member states' commitment to ensure a high level of human health protection when it comes to the regulation of healthcare professions, which are also among the most mobile professions in Europe. As we have repeatedly stated, when it comes to patient safety, economic concerns are secondary."

PGEU President Jesús Aguilar Santamaría adds that "member states must ensure access to high quality health care services and safe supply of medicines according to the public health needs of their national demographic, geographical and cultural realities. We believe this compromise will allow member states to continue protecting public health."

CPME President Dr Jacques de Haller concludes that "this result is a clear confirmation that Member States can continue to put patient safety first. We now look to member states to find an approach which uses the margin of discretion the Directive grants. The health professions will continue to monitor the implementation."

*The **Council of European Dentists (CED)** is a European not-for-profit association representing over 340,000 dental practitioners across Europe through 32 national*

*dental associations and chambers in 30 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED aims to promote high standards on oral healthcare and dentistry with effective patient-safety centred professional practice, and to contribute to safeguarding the protection of public health. The CED is registered in the Transparency Register with the ID number 4885579968-84.*

*The **Pharmaceutical Group of the European Union (PGEU)** is the association representing community pharmacists in 33 European countries. In Europe over 400,000 community pharmacists provide services throughout a network of more than 160,000 pharmacies, to an estimated 46 million European citizens daily. PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.*

*The **Standing Committee of European Doctors (CPME)** represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

- *We believe the best possible quality of health and access to healthcare should be a reality for everyone.*
- *We see the patient-doctor relationship as fundamental in achieving these objectives.*
- *We are committed to interdisciplinary cooperation among doctors and with other health professions.*
- *We strongly advocate a 'health in all policies' approach to encourage cross-sectorial awareness for and action on the determinants of health.*

## Brexit Update

The UK Government has reached provisional agreement with the European Commission on the details of the proposed transition period which will begin once the UK formally leaves the EU on 29 March 2019. Under the terms of the deal, which is due to be formally signed towards the end of the year, the transition period will end on 31 December 2020 and EU nationals arriving in the UK during the transition period would receive the same rights as EU nationals in the UK before. However, we understand that the status of Northern Ireland post-EU exit remains a sticking point in the negotiations. Agreement on this issue must be reached in order for the wider Withdrawal Agreement to be signed.

In the meantime, the European Commission has published its draft guidelines on the future post-Brexit relationship between the EU and the UK. The new guidelines provide the following framework for future EU-UK relations:

- The EU “will preserve its autonomy in decision making”, so the UK will be excluded from participation in EU institutions and decision making of EU bodies, offices and agencies
- A future free trade agreement will be “balanced, ambitious and wide-ranging” and finalised once the UK has left the EU

- Trade in goods should cover all sectors, maintain zero tariffs and rules of origin
- A framework for voluntary regulatory cooperation
- Market access to provide services under host state rules
- Reciprocity and non-discrimination, coordination of social security, recognition of professional qualifications and adherence to human rights
- Dialogue, consultation, coordination, exchange of information, and cooperation mechanisms, including a Security of Information Agreement.

The EU foresees a Free Trade Agreement between the UK and EU which would contain a framework for the recognition of professional qualifications (RPQ).

In March the UK government also confirmed that it would seek a continued framework for the recognition of qualifications.

Negotiations on both the Withdrawal Agreement and the future relationship will continue over the summer.

## European health community issues key questions Article 50 negotiations must answer for patients and public health

The European health community has warned that time is running out to secure patients’ interests in Brexit negotiations. With Phase 2 of the negotiations well underway, health groups across Europe have drawn up a [list of crucial unanswered questions](#) that must be answered by the EU and UK negotiations to ‘put patients first’ in the negotiations. Organisations included in the discussions include the [European Patients Forum \(EPF\)](#), the [European Federation of Dental Competent Authorities and Regulators \(FEDCAR\)](#) and the [European Federation of Pharmaceutical Industries and Associations \(EFPIA\)](#).

Health groups have published the questions in light of the discussions by the EU27 on the draft guidelines for the future relationship between the UK and EU. Some of the key questions are:

- How will a trade agreement ensure sufficient and timely supply of medicines and medical devices for both EU and UK patients?
- In the event of a ‘no deal’ Brexit, how would EU27 national governments avoid that public health be affected across the EU?
- How will the UK and the EU come to an agreement to ensure the future drug licensing system does not exacerbate delays in access to the most innovative treatments for patients, both in the UK and across the EU?
- How can EU and UK patients benefit from the pooling of scarce expertise in rare and complex diseases under European Reference Networks?

[More information can be found here.](#)

## Keeping Europe Healthy: Brexit and the European Medical Profession

Paul Laffin, BMA EU Public Affairs Manager

The message from experts at the BMA event [Keeping Europe Healthy: Brexit and the European Medical Profession](#) held in the European Parliament couldn't have been starker: Brexit is a threat to Europe's health.

Hosted by [Wajid Khan MEP](#), and run in conjunction with the BMA's

European partners, speakers were clear about the threat that Brexit poses to their profession and the patients that they serve across the continent.

MEPs and diplomats from across the EU 27 members states heard [Dr Jacques de Haller](#), President of the CPME Standing Committee of European Doctors, call on negotiators to recognise the medical profession's special status and elevate its concerns above the politics of Brexit.

[Professor Trevor Duffy](#), Chair of the IMO's (Irish Medical Organisation) International Committee, described how, across both sides of the Irish border, 'over decades we've developed a system that is mutually dependent.'

President of the EJD (European Junior Doctors' Association), [Dr Kitty Mohan](#), startled attendees with her analysis of how Brexit is already damaging the pan-European workforce and the cross-border nature of medical education and training.

Portuguese national, [Dr Miguel Reis Ferreira](#), a clinical research fellow in uro-oncology at the Institute of Cancer Research in London, demonstrated clearly how collaborative projects involving both UK and EU researchers delivered better outcomes than those which were conducted without such cross-border working.

Mairead McGuinness, an Irish MEP and Vice-President of the European Parliament, couldn't have been clearer in her support for a solution which doesn't threaten Europe's health as "both Ireland and the EU have a lot of skin in the game."

She was, however, equally forthright in her view that the UK's decision to diverge from the EU's regulatory framework, and the limited amount of time remaining to find solutions, mean that such an outcome might simply not be possible.

Speaking before the referendum, Michael Gove, UK Minister for Environment, Food and Rural Affairs and leading Brexit advocate stated that "people in this country have had enough of experts". Having heard from a range of medical experts at our event, I can only hope that this view isn't shared on the EU side.



## Health systems in the EU: Commission publishes report on primary care

The European Commission EU Expert Group on Health Systems Performance Assessment (HSPA) has published a report entitled [A new drive for primary care in Europe: rethinking the assessment tools and methodologies](#) to help policy makers and health practitioners to set objectives and measure progress towards improving primary care services for the benefit of patients.

The report examines core aspects of well-performing primary care systems, focusing on their key functions such as access, coordination of care and continuity of care. The analysis confirms that performance assessment in primary care paves the way for better health outcomes, and improves the overall health system. However, there is significant scope to advance primary care performance assessment in Europe.

The report puts into focus three main challenges which should be addressed to advance performance assessment in primary care: 1) the complexity of the performance aspects of primary care; 2) difficulty in integrating assessments into policies; and 3) pitfalls associated with a culture of excellence. To ensure that performance assessment maximises its potential, the report recommends the following seven essential elements for building primary care performance assessment:

- 1 **Improve primary care information systems**
- 2 **Embed performance assessment in policy processes**
- 3 **Institutionalise performance systems**
- 4 **Ensure accountability**
- 5 **Consider patients' experience and values**
- 6 **Take advantage of adaptability, which performance assessment can support in the moment of change for primary care**
- 7 **Support a goal-oriented approach through the better use of professional and contextual evidence**

For more information on the EU Expert Group on HSPA [please follow this link](#).



### Q1

#### Implementation of the alert mechanism

Annie Schreijer-Pierik MEP has questioned the EC on the fact that, two years after its introduction, the fitness to practise alert mechanism is not yet in use in ten EU member states and asked what action the EC intends to take. In response, the EC stated that a number of infringement procedures have been launched for incomplete transposition of Directive 2013/55/EU and that all of the member states concerned have communicated completion of transposition measures. The EC is currently examining the notified legislation, including the implementation of the alert mechanism.

[Find out more here](#)

### Q2

#### Recognition of third country qualifications

A number of MEPs have questioned the EC on the procedure for recognising professional qualifications awarded outside the EU and asked if the EC plans to address anomalies in the system. The recognition of medical qualifications obtained outside the EU is governed by the member states' domestic rules, which means that the conditions for acquiring the right to practice (financial costs and time required), differ significantly from country to country. In response, the EC confirmed that when professional qualifications are obtained in a non-EU country, EU recognition rules do not apply and that recognition can be granted according to the national rules of that member state. The Commission is not in a position to intervene in these procedures.

[Find out more here](#)

### Q3

#### Otorhinolaryngology

Roberta Metsola MEP has questioned the EC on the possibility of updating the reference in the Annex to the Directive on the mutual recognition of professional qualifications for the specialty of otorhinolaryngology. One of the key sub-specialisms has evolved to become 'Head and Neck Surgery', which, among other things, involves surgical treatment of cancer in the head and neck area. The current minimum training period for otorhinolaryngology is listed as three years, however, changes to the curricula and training has resulted in significantly longer training times in a number of member states. In response, the EC stated that it had not received a request to amend the reference in the annex to 'Otorhinolaryngology – Head and Neck Surgery' but that a request could be submitted if at least 2/5 of member states notify their interest in changing the name and training duration of the specialty.

[Find out more here](#)

### Q4

#### Recognition of optometry qualifications

Fernando Ruas MEP has questioned the EC on the recognition of optometry qualifications across the EEA and the difficulties posed by the fact that qualifications are not automatically recognised under EU law. In response, the EC stated that it is aware that the regulation of the profession of optometrist differs across the EU, from reservation of activities to a different category of professionals to complete non-regulation of the profession. However, member states are obliged to assess the level of qualification of an optometrist applying to join the register in a host member state by taking into account any professional experience. In case of substantial differences, imposition of compensation measures is allowed but the recognition of professional qualifications directive also provides for partial access, on a case-by-case basis, when certain conditions are met.

[Find out more here](#)

### Q5

#### Regulated professions in France

Dominique Martin MEP has questioned the EC on the number of applicants requesting to have their qualifications recognised in France and which countries have the highest number of applicants rejected. In response, the EC stated that the regulated professions' database shows that in 2016, 142 out of 1,271 recognition decisions made by France were negative towards citizens from other member states of the EU, Norway, Iceland, Liechtenstein and Switzerland.

The main countries concerned with negative decisions from France were Spain (30 requests refused), the United Kingdom (23 requests refused), Belgium (22 requests refused), Italy (15 establishment requests refused), Portugal (13 requests refused) and Germany (9 requests refused). While, other countries affected in smaller proportions were Romania, Hungary, the Netherlands, Austria, Czech Republic, Sweden, Luxembourg and Poland.

[Find out more here](#)

### Quality in Dental Education

*David O'Flynn, Registrar, Dental Council of Ireland,  
Chair of FEDCAR*

On 20 April 2018, the Dental Council of Ireland hosted and chaired the spring meeting of the Federation of European Dental Competent Authorities and Regulators (FEDCAR). At the meeting accreditation of dental education was at the top of the agenda. This is the first time the main stakeholders representing the regulators, dental educators, representatives of the dental profession and students have met to discuss the issue at an EU level.

It was acknowledged that, in order to trust the system for mutual recognition of dental qualifications, it was important to have assurances of the quality of dental education. At present there is no Europe-wide obligation or common minimum standards for member states to regularly assess the quality of dental training.

The concerns are well grounded. In 2016, [the European Dental Students Association \(EDSA\) published the results of its survey of clinical practice in EU dental schools](#). It found that 10% of respondent final year students had never treated a patient during their training or practiced in a dental clinic or hospital. The survey also found that one in three respondents had never completed a crown surgery and one in two had never performed endodontic treatment (root canal therapy).

The Association of Dental Educators in Europe (ADEE) found in its [2016 Survey of Dental Education in Europe](#) that 'respondent dental schools across Europe have developed programmes of study with differing ways of using time for didactic, simulation and clinic/patient care'. The concern for regulators is that there is no reasonable assurance that new students have an appropriate standard of training at the time of registration. Currently accreditation of the 193 dental schools in Europe is at national level.

There are different models operating at present: some, like the Irish model, where the regulator assesses the quality of dental education independent of the university quality systems; whereas some consider the standards as part of the university quality assurance, sometimes it is through a central ministry. FEDCAR respects the autonomy granted to member states under the Article 165 of the EU Treaty. But it is important for both patient safety and the function of a Single Market if, in future, there exists an obligation for member states to ensure a mandatory system of a 'public, regular and independent' assessment or accreditation of their dental training programmes.

FEDCAR, ADEE, ESDA and Council of European Dentists (CED) have agreed to collaborate to see if it is possible to make a joint submission to the European Commission on this matter.

### Outcomes of the CPME General Assembly and Board meeting

On 14 April 2018, delegates from 32 National Medical Associations attended the biannual General Assembly and Board meetings of the Standing Committee of European Doctors (CPME). The following proposals and policies were adopted:

- The CPME statement on the European Commission proposal for a Regulation on Health Technology Assessment (HTA). You can read [the full statement here](#).
- The CPME policy on trans fats – you can read [the full statement here](#).
- The General Assembly of the Standing Committee of European Doctors admitted [the Medical Women's International Association \(MWIA\)](#) as a new CPME associated organisation member.



## Developments in EU regulation

### How the General Data Protection Regulation (GDPR) will specifically affect healthcare

The EU's [General Data Protection Regulation \(GDPR\)](#) began on 25 May 2018. The GDPR is changing more than data compliance in Europe; it is changing the way businesses operate, affecting how and when they interact with the data of EU residents. One industry that will be held to higher standards is healthcare.

The healthcare industry can expect a variety of new challenges when it comes to gathering and protecting the personal data of EU residents. The new legislation aims to build upon common and current personal information protection, working to ensure that data is protected across all processing activities and endpoints.

#### What does it mean for healthcare organisations?

There are a number of requirements that are healthcare specific that healthcare organisations need to comply with in order to adhere to the new GDPR policies. This includes all personal data has to be gathered in accordance with [Article 5 of the GDPR](#) meaning that the data:

- Must be collected for specified, legitimate and explicit purposes and not processed in a way which is incompatible with them
- Processed lawfully, fairly and in a transparent manner
- Processed to ensure appropriate security of data
- Adequate, relevant and limited to what is necessary in relation to the purposes for which it is processed
- Accurate and kept up-to-date
- Kept in a form which permits identification of data subjects for no longer than is necessary for the purpose for which it is processed
- Controlled by a controller who is responsible for the data and able to demonstrate compliance.

Failure to comply with the GDPR can mean serious fines for healthcare organisations up to €20 million.

PRIVACY LAWS

## Pharmacists start revalidation

In March 2018, the General Pharmaceutical Council (GPhC) commenced the roll out of revalidation for pharmacy professionals in Great Britain. This is a momentous change for the sector and, as such, has been developed in full collaboration with pharmacy professionals, professional organisations, charities and patients over a number of years. It has been met with strong support throughout.

Revalidation models are currently used by other health professions throughout the UK including doctors, nurses and midwives. However, pharmacy professions are distinct from other professions, and from each other, so the proposed framework for pharmacy professionals is similar in name, but fundamentally different in design, to other models so that it works well for pharmacy.

There are a range of benefits in asking professionals to revalidate. Indeed it is one of the ways that the GPhC can provide assurance to the public that their trust in pharmacy professionals is well placed. Revalidation builds upon what pharmacy professionals do – as part of their



work and development – to make sure they remain fit to practise through using, maintaining and developing their professional knowledge, attitudes and behaviours. We know that health and social care has changed considerably to meet the changing needs of the population, and it will continue to do so. Revalidation will help both professionals and the regulator to adapt to these changes. To find out more about revalidation visit the [GPhC website](#) or watch this [short video about revalidation](#)'.

## NMC figures continue to highlight major concern as more EEA nurses and midwives leave the UK

Figures from the UK [Nursing and Midwifery Council \(NMC\) register](#) show a significant rise in the number of European Economic Area (EEA) nurses and midwives leaving the register. Between April 2017 and March 2018, 3,962 people left the register - an increase of 29%.

In parallel with EEA trained nurses and midwives leaving the register, there continues to be a drop in those joining the register from the EEA. Over the same period 805 EEA trained nurses and midwives joined the register compared

with 6,382 the year before – a drop of 87%. However, there are many reasons which could impact on the number EEA trained nurses and midwives joining the NMC register, including the introduction of an English language proficiency requirement in 2016.

In contrast, the NMC saw an increase of UK and non-EEA trained nurses and midwives between April 2017 and March 2018.

### Between March 2017 and March 2018:



The number of nurses and midwives **from the UK** increased by **1,321**



The number of nurses and midwives **from the EEA** decreased by **2,909**



The number of nurses and midwives from **outside the EEA** increased by **1,093**

The NMC carried out a survey with 3,496 people leaving the register and asked them to select their top three reasons for leaving. Of the total number of respondents, 227 were from the EEA.

As highlighted in the table below, the top three reasons

given by EEA trained nurses and midwives for leaving the register were that they are leaving or have left the UK, that Brexit had encouraged them to consider working outside the UK and that their personal circumstances had changed.

### Top reasons that EEA nurses and midwives gave for leaving the register:



I am leaving or have left the UK

**59%**

gave this as one of their top 3 reasons



Brexit has encouraged me to consider working outside the UK

**47%**

gave this as one of their top 3 reasons



My personal circumstances have changed

**22%**

gave this as one of their top 3 reasons

## NMC introduce new Education Standards for registered nurses

In May 2018 the UK Nursing and Midwifery Council (NMC) published its new [Education Standards](#) for registered nurses. The new standards, which will come into force in January 2019, are designed around the skills and knowledge required by the next generation of nurses.

Changes to the new standards include both standards for proficiency for nurses and standards relating to education and training.

The standards for proficiency include the minimum standards a nurse will need to meet to be considered capable of safe and effective practice, both in terms of initial entry onto the register and their ongoing practice.

The NMC approve nursing programmes in the UK and the new Standards will have to be embedded within all the nursing programmes the NMC approve. This means that the

link between the education programmes and the experience of students and what is expected from them after they have graduated will be strengthened. Additionally, it will tie the standards of proficiency in with the requirements set out in [the Code](#) (which outline what the NMC require of nurses and midwives) to clearly establish the requirements and standards nurses and midwives must meet throughout their careers.

In addition to the new Standards, the NMC is undertaking several other projects which are linked to this. These include consulting on the role of the new regulated profession, Nursing Associate, which will be introduced in January 2019 and a review of the overseas application process for non-EEA applicants. An important motivation for the review is to ensure that the registration process reflect the new Standards.

## NMC to overhaul its fitness to practise strategy to support a learning culture and enhance patient safety

The NMC is in the process of updating its fitness to practise strategy, [Fitness to Practise: 'Ensuring patient safety, enabling professionalism](#). The updated strategy was consulted on between April and June 2018 and the proposed changes aim to encourage an open and a learning culture, and to support nurses and midwives to address concerns about their practice.

A main motivation behind updating the strategy is that the NMC want to encourage nurses and midwives to speak up at the earliest opportunity when things go wrong and see the fitness to practise process as an opportunity to learn and reflect, rather than appropriate blame.

The changes are based on ten key principles, which address factors such as the purpose of hearings, the need to give nurses the chance to remediate, how employers can deal with complaints and the importance of considering the context of a case. In cases where there's no dispute about what happened or what sanction should be applied, the NMC plan to conclude cases without the need for a public hearing. In addition to this the NMC included proposals on how to better help employers deal with.



### International regulatory approaches to telemedicine Competence 2017

*Sarah Barker, International Manager, GMC*

The UK General Medical Council (GMC) recently published a research report looking at regulatory approaches to telemedicine around the world.

We commissioned this research, from Europe Economics, because we wanted to find out more about how UK health regulators and regulators overseas regulate doctors, healthcare providers and healthcare services, where the services are provided remotely. We wanted to compare how this works where the services are provided within the same jurisdiction (such as within the UK) and across jurisdictions (for example, when the doctor is physically based in France but the patient is in the UK). We also wanted to understand more about how other industries regulate professionals who provide services remotely - for example, financial services, engineering or surveying.

#### What were the key findings?

Definitions of telemedicine are complex and multifaceted with some variability across countries. Some territories, for example in North America, require doctors to be licensed in the jurisdiction of the patient, while many European regulators tend to require doctors to be licensed in their own jurisdiction.

Most regulators that took part in the research emphasised that doctors must maintain the same standards of care when treating a patient through telemedicine as they would when face to face. Some also offer specific guidance around telemedicine, e.g. maintaining patient records and maintaining confidentiality.

The full report is [available here](#).



### Number of overseas doctors wanting to work in UK increases

Hundreds more overseas doctors are applying to work in the UK each year, [according to figures](#) released by the General Medical Council (GMC) (see Table 1 below).

The GMC assesses the skills of non-EEA doctors who want to join the UK medical register, and is adapting to deal with an increased demand in the numbers applying to take the practical exam they must pass before they can work in the UK.

Demand for the multiple choice and practical Professional and Linguistic Assessments Board (PLAB) exams means that the GMC is now adding additional test dates at weekends, in a move aimed at supporting a healthy supply of doctors into UK practice.

Last year, nearly 3,000 doctors travelled from across the world to the GMC's offices to sit the practical assessment to work in the UK. This year the GMC estimates that more than 5,000 doctors will take the exam.

The increased interest to work in the UK is welcome news for the medical workforce as evidence suggests that the supply of new doctors to the UK is not keeping up with changes in patient demand.

Table 1

#### PLAB 2 Practical examinations

A table showing the number PLAB 2 practical examinations taken between 2011 and 2017.

Year	Number of PLAB tests taken
2011	2,636
2012	1,735
2013	1,779
2014	1,728
2015	2,257
2016	2,454
2017	2,966

## Registration now open for the IAMRA 2018 Conference in Dubai!

Registration is now open for the 13th International Association of Medical Regulatory Authorities (IAMRA) 2018 Conference to be held in Dubai.

The Conference 'Empowering Regulation on Innovation and Evidence' will be held from 6-9 October 2018. The Conference will provide an opportunity for medical and health regulators, policy makers, and academics to come together and share ideas and experiences. Subthemes of the conference include:

- Innovative regulatory models
- Medical workforce
- Safe practice and quality
- Medical education.

Find out more details on [www.iamra2018.com](http://www.iamra2018.com)



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## Conference Theme: Empowering Regulation with Innovation and Evidence.



## Pakistan Medical and Dental Council disbanded

In January 2018, the Pakistan Supreme Court disbanded the governing body of the Pakistan Medical and Dental Council (PMDC), finding that the Council was functioning unlawfully because the PMDC (Amendment) Ordinance 2015, under which it had been operating, had lapsed.

The Supreme Court has established [an interim 'ad-hoc' committee](#) to take charge of the PMDC's affairs. The nine-member committee, headed by Justice Shakirullah Jan,

has been asked to look into the operations of PMDC and recommend improvements and legal reforms.

The Educational Commission for Foreign Medical Graduates (ECFMG) has contacted the PMDC and it is understood that the PMDC will continue normal operations, including verifying medical credentials for ECFMG, whilst the changes and reforms are underway.

## Upcoming events

**22 June 2018**

[European Network for Medical Competent Authorities \(ENMCA\) meeting](#)

Paris, France

**10-12 September 2018**

[The International Forum on Quality and Safety in Healthcare](#)

Melbourne, Australia

**06-09 October 2018**

[IAMRA conference](#)

Dubai, United Arab Emirates

**09-10 November 2018**

[CPME Board and General Assembly meeting](#)

Geneva, Switzerland

**26 November 2018**

[European Network for Medical Competent Authorities \(ENMCA\) meeting](#)

Vienna, Austria

**04 February 2019**

**HPCB conference 2019**

Dublin, Ireland

## Newsletter and Updates

[Health and Care Professions Council \(UK\)](#)

[Nursing and Midwifery Council \(UK\)](#)

[European Federation of Nurses](#)

[European Federation of Dental Regulators eNews](#)

[General Dental Council \(UK\)](#)

[General Chiropractic Council](#)

[European Commission DG GROW](#)

[Health-EU e-newsletter](#)

[IAMRA newsletter](#)

[European Parliament internal market committee newsletter](#)

[Professional Standards Authority \(UK\) newsletter](#)

[General Pharmaceutical Council \(UK\)](#)

[European Social Network](#)

[Association for Dental Education in Europe \(ADEE\)](#)

[French Order of Doctors](#)

[General Medical Council \(UK\)](#)

[CORU \(Ireland\)](#)

[PSI newsletter](#)

If you would like to contribute a piece to the next Crossing Borders Update please contact the **HPCB secretariat**.