Healthcare Professionals Crossing Borders
Portugal Agreement

This Agreement was made in Lisbon, Portugal, at the 2007 Autumn meeting of the Healthcare Professionals Crossing Borders partnership.

Healthcare Professionals Crossing Borders is an informal partnership of professional healthcare regulators in Europe.

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An Agreement of the Healthcare Professionals Crossing Borders partnership made in Lisbon, Portugal on 8th October 2007

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b) The pursuit of safe and high quality practice by health professionals should shape the continued development of healthcare 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[1] – may contribute to the effective development of healthcare regulation in Europe, through a series of European level discussions.

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Transparent and Accessible Healthcare Regulation:

a) Competent authorities should run a website signposted and 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.

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[1] Taken from the Legal Affairs Committee of the European Parliament Report on Better Regulation in the EU 2.7.07 (pg 5 para 1) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2007-0273+0+DOC+PDF+V0//EN

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 IMInet system 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.

Background

The Healthcare Professionals Crossing Borders initiative aims to make a contribution to patient safety and high quality healthcare in Europe through effective collaboration between European health regulators (competent authorities).   The initiative brings together regulators from across the European Economic Area (EEA), and relevant EU-level networks and associations, to identify and implement collaborative approaches to professional healthcare regulation in the context of free movement of healthcare professionals in Europe.

The increasing mobility of health professionals and patients in Europe means it is vital that regulators, patients and citizens have assurance that all health professionals are fit and safe to practise. There are immense benefits to health systems in Europe and the health of European citizens from the free movement of health professionals, most of whom make a strong contribution to delivering high quality healthcare. There is also the potential for patients to benefit from access to treatment in other European member states, where free movement rules allow.

Regulators must work together to contribute to high quality health care in Europe through maintaining and improving standards of practice and ensuring professionals who are, or may pose, a risk to patients cannot move between countries without host regulators being made aware of their disciplinary and practise record.   Indeed, they must guard against the European single market being exploited by those healthcare professionals who seek to avoid regulatory control or disciplinary action in their home country by moving elsewhere.

The 'Crossing Borders' initiative formally commenced in 2005 during the UK Presidency of the EU and regulators have, since then, worked in partnership to implement a series of actions contained within the 'Crossing Borders' Edinburgh Agreement. The Portugal Agreement builds upon this work and sets out a number of new agreements to be implemented by 2009.

Below is a summary of key Healthcare Professionals Crossing Borders' milestones to date:

Dutch Presidency of the EU, 2004
The Healthcare Professionals Crossing Borders initiative began in 2004 as a patient safety initiative of the Dutch Presidency of the EU. In December 2004 regulators of all health professions from across the EEA met in Amsterdam. They made a commitment to work together, to improve registration and disciplinary information exchange between competent authorities, to provide assurance that health professionals moving from one member state to another were fit and safe to practise.

UK Presidency of the EU, 2005
The subsequent UK Presidency of the EU adopted patient safety as a key priority. Following many months of collaboration with EEA healthcare regulators, the Department of Health in England and the Alliance of UK Health Regulators on Europe (AURE) hosted the European Consensus Conference in October 2005. At this conference, at which most EEA member states were represented, the 'Crossing

Borders' Edinburgh Agreement was finalised and agreed.

Edinburgh Agreement, 2006-2007

The Edinburgh Agreement set out a number of actions which regulators agreed to implement by the coming into force of Directive 2005/36/EC on Recognition of Professional Qualifications, in October 2007.

The Agreement included actions on the following themes:

- Implementing the European Template for a Certificate of Current Professional Status.

- Dealing with information exchange on difficult cases on a case-by-case basis.

- Supporting information exchange between health regulators.

Regulators also met at a series of EU-wide Crossing Borders meetings held in Brussels, Helsinki and Berlin to discuss and agree areas of further collaboration. They collaborated on a joint-statement submitted in response to the European Commission's consultation on 'Community Action on Healthcare Services in Europe' in January 2007. The Crossing Borders initiative was recognised and welcomed by the European Parliament in its report on Health Services[2], in May 2007.

Portugal Agreement, 2007

The Portugal Agreement replaces the Edinburgh Agreement by building on the work already undertaken by the Healthcare Professionals Crossing Borders initiative and establishing further areas of regulatory collaboration between EEA regulators of health professionals. This new Agreement was finalised at a 'Crossing Borders' meeting held in Lisbon, during the 2007 Portuguese Presidency of the EU. Healthcare regulators will work to implement the actions contained herein, as appropriate, during 2007 and 2008 and the Agreement will be implemented by October 2009. A further review of the Healthcare Professionals Crossing Borders initiative will take place in late 2009.

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[2] European Parliament report on 'The exclusion of health services from the Services Directive' P6_TA(2007)0201

1. Identifying Shared Principles of Regulation

The Edinburgh Agreement was developed in the spirit of mutual trust between professional healthcare regulators within the EEA and the acknowledgement that each regulatory authority is aiming to uphold safe and high quality standards of healthcare practice and protect patients from those professionals whose practice puts patients at risk.

While all regulators would share the premise that professional healthcare regulation is in place primarily for the purpose of public protection, more generally regulatory approaches in Europe differ from country to country. The nature and structure of regulatory bodies varies, for example some are government departments while others are independent of government; some fulfil all regulatory functions while others share regulatory responsibility with other organisations. Despite the often complex differences, increasingly EEA regulators need to work closely to meet the obligations of European law in the context of the single European market and free movement of regulated healthcare professionals - and ensure patient safety is maintained.

Indeed, as healthcare professionals choose to benefit from rights of free movement, and as the potential for increased patient mobility in Europe becomes realised, the need for all stakeholders to fully understand the variety of regulatory approaches and models becomes more important. In this light there may be benefits from healthcare regulators working together to broadly consider whether there are shared principles on which professional healthcare regulation in Europe is, or should be, based.

Prior to the finalisation of the Edinburgh Agreement in 2005, European competent authorities developed a number of common assumptions about the principles and values of professional healthcare regulation in Europe. These were that regulators will:

- contribute to a high level of quality in healthcare and the security and protection of patients;

- facilitate professional mobility and provide regulatory assurance to the public benefiting from patient mobility;

- ensure public confidence in healthcare professionals and their regulation;

- avoid unnecessary bureaucracy;

- presume innocence until found guilty in all cases of investigation into professional practice or allegations of criminal activity;

- respect personal data protection legislation provided for in relevant European Directives[3] and national legislation.

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[3] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communication sector.

There is value in re-visiting these principles and values and assessing whether they are indeed shared by regulators across Europe. It would also be useful to consider whether there are additional regulatory concepts and values that could be emphasised by healthcare regulators in the further development of their regulatory approach to further contribute to patient safety and good regulation in Europe and contribute to the effective working of the Single Market.

Agreement 1:

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 healthcare 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[4] – may contribute to the effective development of healthcare regulation in Europe, through a series of European level discussions.**

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2. Transparent and Accessible Healthcare Regulation

The Healthcare Professionals Crossing Borders partnership has worked extensively to deliver the Edinburgh Agreement, which sets out a range of practical collaborative initiatives for regulatory information exchange between professional regulators across Europe. These include the development and implementation of a European template for Certificates of Current Professional Status, the development of a European Memorandum of Understanding on Case by Case and Proactive Information Exchange between European regulators, and the continued management and development of a web-portal for European health regulators at www.healthregulation.org

Beyond this initial work, there is opportunity for further collaboration in the area of regulatory information provision. This includes information about the workings of regulation and also about regulated professionals for competent authorities, patients, employers and the public and other professionals. Indeed, as well as the information already required by competent authorities for the registration of EEA healthcare professionals, patients seeking treatment in other European member states should also have access to good quality information to enable them to exercise informed healthcare choices. An important dimension of information provision for all these audiences is accessibility and transparency.

The concept of 'transparency' is recognised within Europe and internationally as a feature of good regulation and of patient centred-healthcare. In 2003, the UK's Better Regulation Commission adopted transparency as one of its five principles of regulation stating that *"Regulators should be open, and keep regulations simple and user-friendly."*[5] The OECD, in 2005, also established, as a guiding principle on regulatory quality, that "*regulations, regulatory institutions charged with implementation, and regulatory processes are transparent and non-disciminatory."*[6] In 2006 EU health ministers similarly agreed that health systems should *be "publicly accountable and ensure good governance and transparency."*[7]

Making more information about regulation and about regulated professionals publicly available undoubtedly contributes to good, transparent and accountable healthcare regulation. It can also demonstrate that regulatory processes and procedures are fair, open and free from unfair discrimination. Indeed, general public information about professional healthcare regulation can contribute to a better common understanding of how professional healthcare regulation works, the role and purpose of regulation, and raise greater awareness of the regulatory accountability of healthcare professionals.

Transparent and accessible information about regulated professionals can enable the public, patients, other competent authorities and employer organisations to

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[5] 'Principles of Good Regulation' p5 (Better Regulation Task Force, 2003)
[6] 'OECD Guiding Principles for Regulatory Quality and Performance' p.5 (OECD, 2005)
[7] 'Council Conclusions of Common values and principles in EU health systems', Employment, Social Policy, Health and Consumer Affairs Council, 1-2 June 2006.

identify those professionals who are appropriately registered within a specific jurisdiction - and potentially alert them to those who are not. Also, the nature and scope of health professions may sometimes differ between member states. The role of some professions may be understood and practised differently in other member states, and some professions may not exist or be regulated everywhere in the EEA. In this context, transparent information about a practitioner's expertise and scope of practice can assure patients that those they consult are qualified and knowledgeable in their profession or specialty.

A broad range of information is already made available to patients and the public by certain regulators. Some, for example, have established web-based searchable lists of professionals registered within their jurisdiction that provide real-time information about those professionals. Others make their standards, codes and guidance publicly available or publish notifications of forthcoming disciplinary hearings and subsequent decisions on their websites. In addition, some clearly articulate which regulatory functions they fulfil, their registration process or the mechanism by which patients can make complaints. However, the extent to which healthcare regulators in Europe are transparent and accessible in their public information provision is diverse.

If healthcare regulation has patient safety at its heart, patients and the public have the right to transparent and accessible information. This could include access to information assuring patients that the health professionals they will consult are registered to practise and are qualified or experienced in a particular area of healthcare or specialty, and if they have been subject to any recent disciplinary action.   In the unlikely event that things go wrong, during the consultation or treatment process and if there is cause to complain, patients, contractors and the public also need assurance that they have recourse to effective regulatory complaints procedures and that fair and non-discriminatory action will be taken against those professionals whose practice falls short of acceptable standards. Therefore, information transparency and accessibility contributes to patient safety, and may contribute to the effective working of the single market, by maintaining and enhancing patient and public confidence in healthcare across Europe.

Agreement 2:

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.**

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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 IMInet system and will utilise this information exchange tool in accordance with the provisions for administrative cooperation contained within Directive 2005/36/EC.

3. Competence Assurance of European Healthcare Professionals

A competitive and sustainable European Union is reliant upon a healthy workforce and population. In 2006 EU Health Ministers highlighted the centrality of healthcare to Europe's *"social protection…social cohesion…social justice and sustainable development"*[8]. In fact, European citizens depend on good public health policy and accessible and responsive health systems to maintain a good state of health and to play a full part in European society and economy. Crucial to this is the role of healthcare professionals. Indeed, good public health and healthcare policy, depends upon the competence and performance of healthcare professionals that work within Europe's health systems.

As they move between jurisdictions in Europe, the only assurance member states have that healthcare professionals are up to date and fit to practise their profession is their formal qualifications. Competent authorities must rely on the fact that a professional has previously obtained a particular qualification, as set out in Directive 2005/36/EC, and is not currently the subject of disciplinary proceedings. This situation does not enable regulators to be alerted to instances of poor or impaired performance. Poor performance can be caused by a range of factors and arise at any stage in a healthcare career.

A number of regulatory jurisdictions across the world have developed methods of competence assurance, performance enhancement or assessment for healthcare professionals[9], as a means of ensuring that health professionals continue to practice safely. These methods can also be used to identify those who are departing, or may depart, from acceptable standards. Importantly, good performance relates to the behaviour, communication and professionalism of healthcare professionals as well as their professional knowledge and clinical ability. If these inter-personal skills are impaired they could also cause a professional to depart from relevant regulatory standards and put patients at risk of harm.

Therefore, it is increasingly important and in line with public expectations that healthcare professionals should be able to demonstrate that they remain up to date and competent to practise their profession throughout the career – long after they have obtained their formal qualifications.

European healthcare regulators should have appropriate mechanisms available to them to confirm the current competence and performance of those professionals who practise, or who seek to practise, in their jurisdiction. This could enable all professionals to keep their skills up to date, remain in touch with contemporary

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[8] 'Council Conclusions of Common values and principles in EU Health Systems' (Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg 1-2 June 2006)

[9] These include the Professional Practice and Enhancement scheme of the College des Medecins du Quebec, Canada; the Performance Programme of the New South Wales Medical Board, Australia; the Performance Assessment scheme of the New Zealand Medical Council; and the Maintenance of Certification Programme of the American Board of Internal Medicine, USA.

professional values, and bring benefits of continuous improvement to the practice of healthcare across Europe[10], as well as more effectively contribute to patient safety.

Agreement 3:

   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.**

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   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.**

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[10] Adapted from - C Herbert & P Buckley: 'Responsive and Risk-Based Medical Regulation'. Conference paper prepared for the Regulation, Inspection and Improvement Conference 2006, University of Cambridge.

Healthcare Professionals Crossing Borders – Portugal Meeting, 8th October 2007

Professional healthcare regulators from across Europe met during the 2007 Portuguese Presidency of the EU to consider the Portugal Agreement as a new framework for regulatory collaboration.   Over 60 delegates from 20 European countries attended the Portugal meeting and took part in discussions that considered the content of the proposed agreement.

The main conclusions arrived at during the meeting included the following:

- Delegates were agreed that professional regulation must be robust enough to ensure patient safety.

- There was strong support for the spirit of the Portugal Agreement.

- It was recognised that some aspects of the Agreement are challenging but regulators should work collaboratively to implement it, where they are legally able, and as appropriate to their regulatory context.

- Delegates continued to consider effective information exchange as important, though data protection requirements do inhibit this.

- Delegates agreed that professional healthcare regulation should be transparent and accessible to the public.

- Regulators highlighted their strong support for the European Commission's Internal Market Information System initiative as a mechanisms as a secure web-based communications tool for regulatory authorities across Europe.

- It was also acknowledged that the Portugal Agreement could form the basis for further collaborative work over time.

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