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Alliance of UK Health Regulators on Europe

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Alliance of UK Health Regulators on Europe (AURE)

Response to European Commission Consultation regarding Community action on health services

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Introduction

About AURE

1. The Alliance of UK Health Regulators on Europe (AURE) brings together the 10 health and social care regulators (competent authorities) in the United Kingdom to work collaboratively on European issues affecting patient and client safety. Our purpose is to protect and promote patient safety through effective regulation and ensuring proper standards in the practice of health and social care. It is with this remit that we make our comments on the Commission's consultation. It is not AURE's role to promote the interests of the professions that we regulate - that is a matter for the professional representative bodies or associations.

UK context

2. The consultation document considers the issue of cross border healthcare from a variety of perspectives. As regulators of the health and social care professions in the UK, our concern in responding to the consultation is with the standard of practice provided by individual professionals and with patient confidence in those standards, regardless of whether care is provided in the patient's home state or elsewhere in the European Economic Area (EEA).

3. Our response focuses on the key questions of relevance to AURE and is informed by the fact that the UK has, for many years, been a net importer of healthcare professionals, both from Europe and internationally (see Annex A). We have considerable practical experience of the regulatory implications of high levels of professional mobility. The UK undoubtedly benefits from this high level of mobility, receiving many dedicated professionals who contribute positively to health and social care in this country. Mobility also raises a number of challenges and opportunities that the Commission's consultation presents an opportunity to address. We hope that the following comments will provide a helpful contribution to the debate on health

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services in Europe.

Question 2: What specific legal clarification and what practical information is required by whom to enable safe, high-quality and efficient cross-border healthcare?

4. From a regulatory perspective, there are two issues to be addressed:
 - a. Regulators need access to information that assures them that health professionals registered in their jurisdiction, or seeking registration from another EEA Member State, are fit and safe to practise.
 - b. Patients require information about healthcare professionals, standards of practice and regulatory redress when they access healthcare in another European country.

Regulatory information sharing between competent authorities

5. Most European healthcare professionals are highly competent individuals who make an important contribution to the health and well-being of European citizens and to safe, good quality, healthcare across Europe. Healthcare in Europe also benefits from health professionals being able to work and share their expertise in other European countries. However, there will always be a small minority who seek to exploit rights of free movement in order to evade regulatory control. The European Commission and Member State regulators must work together to facilitate the free movement of the competent majority, while protecting EU citizens against the small number of professionals who may put them at risk.

6. AURE believes it is vital to identify what information and legal clarity is required for safer and better quality healthcare in a European Union of increasing patient and professional mobility. The primary focus for regulators is sharing information about the professional status and competence of individuals who are registered, or who may seek registration, in other EEA Member States, or who hold

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simultaneous registration in several jurisdictions. This exchange of information is fundamental to the protection of patients and the public from health professionals whose competence is impaired.

7. The Directive on Recognition of Professional Qualifications 2005/36/EC already sets out that regulators must cooperate closely on information exchange¹. AURE believes consider that this obligation needs to be strengthened.

8. The Healthcare Professionals Crossing Borders initiative, led by AURE and involving all healthcare regulators in the EEA, aims to develop information sharing solutions in support of this. The initiative has also, informally and on a voluntary basis, established a model for proactive and reactive information sharing between regulators. A number of the participating competent authorities and their networks, participating in Healthcare Professionals Crossing Borders, have also collectively submitted a response to this consultation.

9. Regulators across Europe have welcomed the Healthcare Professionals Crossing Borders initiative and engaged in developing and implementing the Edinburgh Agreement². Indeed, regulators from several European countries have already begun utilising the European Certificate of Current Professional Status. This has the potential to contribute to greater consistency of registration and disciplinary information exchange between competent authorities, at the point of registration, for

¹ Article 56.2 of Directive 2005/36/EC on recognition of professional qualifications states: “The competent authorities of the host and home Member States shall exchange information regarding disciplinary action or criminal sanctions taken or any other serious, specific circumstances which are likely to have consequences for the pursuit of activities...”

² The Edinburgh Agreement was agreed in October 2005 by healthcare competent authorities who gathered in Edinburgh, during the UK’s Presidency of the EU. It sets out a number of agreements to improve and extend information exchange and collaboration between healthcare competent authorities in Europe. These include developing a European Certificate of Current Professional Status and exchanging registration and disciplinary information on a case-by-case or proactive basis where it is in the public interest. The Edinburgh Agreement was developed in the context of Article 56.2 of Directive 2005/36/EC and it is anticipated that healthcare competent authorities across Europe will have adopted the main principles of the Agreement by the coming into force of Directive 2005/36/EC.



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healthcare professions providing cross-border healthcare. It also contributes to patient safety in Europe by providing some assurance for regulators that individuals are fit, competent and safe to practise when they seek registration in another European country. In addition, the initiative has been successful in raising awareness among all healthcare regulators of the importance of effective information exchange between regulatory authorities in the context of Directive 2005/36/EC.

10. At present, Healthcare Professionals Crossing Borders is the only European level forum that brings together competent authorities from all regulated healthcare professions from across the EEA to discuss regulatory matters. This forum provides not only an important opportunity for competent authorities to collaborate more closely but could also become an important sounding board for emerging European policy on healthcare regulation. AURE would like to work closely with the European Commission to further the Healthcare Professionals Crossing Borders initiative.

11. Although the Directive sets out that competent authorities must collaborate on information exchange, this does not go far enough. Our experience shows that the provisions of the Directive are open to varied interpretation based on national approaches to information management and privacy laws. Some regulators, for example, are impeded in the extent of their information exchange because of rigid national interpretations of data protection legislation. This means that patient safety considerations may sometimes be treated as secondary to personal data protection.

12. In a recent well-publicised case, the UK's General Medical Council (GMC) erased Dr B from its register, having concluded that his fitness to practise as a doctor was impaired. The GMC informed other European regulators of the action it had taken, but when Dr B subsequently moved to another Member State, the regulator in that State was unable, under its domestic law, to take action against Dr B on the basis of the GMC's findings. Should Dr B decide to use his position in that State as a launch pad to move elsewhere in Europe, the authorities will have no choice but to confirm to other EEA regulators his good standing in that State despite knowledge of his history

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and standing in the UK.

13. Another case study is that of Dr L who was dually qualified as both a pharmacist and a doctor. He was erased from the GMC's medical register for serious professional misconduct. However, he subsequently resumed practice as a pharmacist in another Member State.

14. Both these cases highlight that it is imperative for competent authorities to be able to hold, request and act on full and up-to-date information about practitioners, such as simultaneous registrations, dual qualifications and registration and disciplinary history, and make this information widely available to other regulators.

15. The diversity in regulatory approach across Europe demonstrates the need for new European legislation to provide clarity as to when regulators must put patient safety ahead of data protection considerations and share information in a collaborative, efficient and transparent way. It is also imperative that regulators have a responsibility to act on such information so as to make patient protection and public safety their paramount concern.

16. AURE would like the European Commission to explore the establishment of a legal duty upon regulators to share information with each other. A duty would ensure that patient safety is central to the free movement of health professionals in Europe.

Information for patients and the public

17. Patients can only exercise a meaningful choice in seeking healthcare in other Member States if they have good information. This includes information about healthcare systems, the cultural context of the host state, and the transfer of responsibility for care when they return home.

18. In the context of regulation, patients need access to information about professional standards, assurance about the professional indemnity of those treating

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them, and information about complaints and redress if things should go wrong. At the most basic level, patients have a right to access information about the registration status and any disciplinary record of their healthcare professionals. At present some regulators are more transparent than others in making information from their registers publicly available and easily accessible.

19. AURE member organisations have publicly accessible and searchable web based lists of registered practitioners. This makes an important contribution to making regulation transparent and provides an easy and accessible way for members of the public, patients and health service contractors to check the registration status of practitioners. All health regulators in Europe should be required to make up-to-date information about their registrants available to the public in this or a similar way.

20. This is important if, for example, a patient obtains medical treatment outside their home state, but requires ongoing care and medication once they return home. When they subsequently request that a pharmacist in their home state dispense a prescription for medication written in another Member State, the pharmacist may need to check the status of the prescribing physician. That is only possible if basic registration information for the physician is readily accessible from the state where the physician is practising.

21. As well as requiring information about the status of regulated professionals, patients also need to be made aware that regulation varies across the EU. Professionals such as chiropractors and osteopaths are regulated in some Member States (such as the UK), but they are not regulated in others. This has significant implications for patient safety in terms of professional education, maintenance of professional standards, registration, complaints and redress. Where a profession is regulated in one country but not another it is vital that regulators are clear who they can approach in that country for information about the practitioner's education, training, professional standards and work history, and any other information relevant



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to professional mobility.

22. Information is also required to ensure that patients clearly understand that there may be differences in the way that healthcare is practiced in different conditions and in the roles and responsibilities of healthcare practitioners. There may also be differences in the scope of practice within the same profession from one Member State to another. The scope of practice carried out by opticians in the UK, for example, is wider than that undertaken by opticians in a number of other EU countries. Similarly, the type of treatment provided in the UK by chiropractors or nurses can, in some countries, only be undertaken by doctors. Patients need to be made aware of where differences lie before they access healthcare in other Member States as the type of care they receive may differ from their expectations.

23. In summary, we believe that high-quality and efficient cross-border healthcare, whether it involves patient or professional mobility, requires accessible information on a wide range of issues such as registration, professional indemnity, complaints mechanisms, professional standards and scope of practice. The European Commission should support regulators and others in making this information available and accessible to the public, to patients, to other regulators and healthcare providers.

Key Recommendations

24. Future European action on cross-border healthcare must balance free movement with an overriding concern for public and patient safety.

25. AURE would like to work closely with the European Commission to further the work of the Healthcare Professionals Crossing Borders initiative and for the European Commission to support the on-going collaboration between competent authorities at EU level.

26. Safe and effective cross-border healthcare requires EU action to

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enhance communication and co-operation between European health regulators. The European Commission should emphasise the importance of regulators exchanging registration and fitness to practise information in any future proposals.

27. The European Commission should propose legislation that imposes a legal duty on regulators to exchange registration and disciplinary information and to act on it, in the interests of public and patient safety.

28. Safe and effective cross-border healthcare must be supported by better and more accessible information for patients and the public.

Question 3: Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare?

Clarity of competent authority role

29. As highlighted above, there is a diverse approach to healthcare regulation across the European Union. In some Member States regulatory functions are fragmented across different organisations or government departments, and in some they are decentralised to the regional level. In others, regulatory responsibilities are integrated within a single organisation. Where there is fragmentation or decentralisation, or both, it may be difficult for regulators to access full registration and disciplinary information quickly and accurately about individuals who are seeking registration elsewhere.

30. The Healthcare Professionals Crossing Borders initiative has already made a contribution to providing clarity on the correct source of information via the Health Regulation website <http://www.healthregulation.org/> (developed, managed and hosted by the UK Health Professions Council) and also through improved networking between healthcare competent authorities in Europe. The European Commission,



however, still has a vital role to play in making comprehensive information about competent authorities publicly available for regulators, patients and the public.

Clarity of regulatory jurisdiction

31. It is important to ensure that there is clarity for patients about where responsibility for regulatory oversight lies when they access healthcare services in their own country or in other Member States. Member States must have the ability to require that health professionals who are delivering services in their jurisdiction are registered in their territory. In the case of temporary provision of services this could be via temporary or pro forma registration. In both circumstances, this will ensure that the professional is within the regulatory jurisdiction of the host state and there is clarity about regulatory responsibility for the professional's activities, for professional standards and for investigating and acting on complaints.

32. The provision of telemedicine raises particular issues in relation to the regulation of cross-border healthcare because the health professional does not physically move jurisdictions in order to provide a service. At present this is mainly an issue for the medical profession but, with the emergence of new technology, it will become increasingly relevant for other health professions. The primary concern must be to ensure the protection of the public and, in the event that things go wrong, enable redress for the patient.

Registration status

33. During the drafting process for both the proposal for a Directive on Services in the Internal Market and the Directive on the Recognition of Professional Qualifications, proposals were made regarding procedures for the authorisation of practice in host states.

34. In our response to those proposals, AURE repeatedly emphasised that authorisation to practise must rest with the appropriate authorities in the host state,



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and must be contingent upon the individual professional satisfying the registration requirements in that state in accordance with the relevant provisions of the Directive. In the field of healthcare, practice without appropriate registration or authorisation by the authorities in the host state presents an unacceptable risk to patient safety. The current consultation makes it important for us to emphasise this principle once again.

Key Recommendations

35. The European Commission has a key role in supporting strong and effective national regulation that promotes high standards of healthcare and professional practice.

36. The European Commission should assist regulators by making comprehensive information about each competent authority in the EEA easily available at European level. Registration and fitness to practise information should also be held in a single place at the national level to enable more effective collaboration and information exchange between regulatory authorities.

37. AURE reiterates its view that where a healthcare professional has moved to another Member State in order to provide services, the host state must be able to require registration. Regulatory responsibility for activities undertaken must lie with the host state. In the case of telemedicine, there must be clarity for patients, professionals and healthcare providers about where regulatory responsibility lies.

38. Any provision allowing healthcare professionals to practise without explicit authorisation from the host Member State constitutes an unacceptable risk to patient safety.

Question 4: Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be



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ensured?

Regulatory responsibility

39. The issue of redress for patients is complex and will generally go beyond the remit of the regulator. However, where a patient is harmed as a result of acts of omission or commission by a healthcare professional whose capability for practice is impaired, the regulator in the host state will have responsibility for taking firm, but fair action against that practitioner to ensure that patient safety is protected in the future.

40. Where the practitioner remains registered in their home state as well as the host state where the incident or events occurred, it must also be possible for the regulatory authorities in the home state to take action against the practitioner to ensure the future protection of its own citizens. This again highlights the general responsibility on all regulators to work cooperatively to provide mutual assurance that regulated professionals are fit and safe to practise.

41. We note that in its consultation document the Commission highlights the importance of 'effective reporting and learning' and 'follow-up to avoid repetition of errors'. These are helpful comments in illustrating the need for regulatory co-operation not only within the country where problems have arisen, but also across borders.

Key Recommendations

42. There must be greater regulatory co-operation between competent authorities not only to ensure patient safety in the country where problems have arisen, but across borders.

43. There must be legal clarity regarding regulatory responsibility in each of the four categories of cross border healthcare. This will help to guard against



duplication of regulatory activity and unnecessary regulatory burdens.

44. Regulation is at its most effective when driven by local and national considerations. The Commission should therefore avoid trying to achieve greater co-operation through increased centralisation of regulatory functions.

Question 6: Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

Common standards within European healthcare

45. It is necessary to recognise the importance of professionalism within regulated professions and the contribution professionalism makes to good regulation nationally and across Europe. It is this professionalism that provides the most effective public and patient protection.

46. It is reasonable to assume that patients may base their expectations about the standards and quality of healthcare they will receive on their experiences in their home country. Within the consultation document there is brief consideration of whether 'there are shared values and principles for health services on which citizens can rely throughout the EU.'³ It is important that competent authorities retain the freedom to develop standards of practice and codes of ethics that are appropriate to local concerns and cultures.

47. AURE does not believe that European level code(s) for healthcare practitioners would be workable or be in the best interests of patient and public safety. However, there may be some common principles that each regulatory jurisdiction could incorporate into their own standards framework. Also, there needs to be clarity over the different ethical principles and/or frameworks governing practice

³ Consultation regarding Community action of health services p4



within each EU country. All patients, professionals and service providers need to be clear about what standards and ethics must be adhered to.

Revalidation of healthcare practice

48. The ability of healthcare workers to practise their profession across Europe is based largely upon the recognition by Member States of their initial qualifications and training and, in some cases, their specialist training. However, 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 their career. Many states are developing systems for ensuring the continuing competence of their healthcare professionals. The Directive on the Recognition of Professional Qualifications acknowledges this development when it states that in view of ‘the speed of technological change and scientific progress, life-long learning is of particular importance for a large number of professions’ and that Member States therefore need to adopt detailed arrangements under which...professionals will keep abreast of technical and scientific progress⁴.

49. In this context, it is no longer sufficient, or in the public interest, for the mobility of professionals to be based simply on the historical acquisition of qualifications. Rather, it is appropriate for host state regulators, in granting access to medical practice, to be able also to take account of the demonstration of ongoing competence to practise, as attested by the home state regulator.

50. AURE recommends that in bringing forward proposals for action on health services the European Commission should acknowledge these developments and incorporate appropriate measures to reinforce the current arrangements for the recognition of professional qualifications.

⁴ Directive on recognition of Professional Qualifications p39 of the preamble.



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Language competence

51. Healthcare professionals must be able to communicate effectively with their patients and with other members of the healthcare team if they are to provide high quality and safe care and ensure informed consent is acquired before commencement of treatment. This requires healthcare professionals to be proficient in the language or languages of the country in which they are working.

52. Although EC law enables European regulators to be satisfied about an individual's professional qualifications before he is registered and able to take up practice in a host state, regulators are not currently permitted to satisfy themselves about the individual's language proficiency.

53. Assessing an individual's language proficiency is sometimes dismissed as a matter for employers, not regulators. This ignores the fact that many healthcare professionals are independent practitioners. Nor is it sufficient to leave it to the market to determine whether an individual has the level of language proficiency necessary to succeed.

54. European legislation must be amended to allow healthcare regulators across Europe to establish at the point of registration that a professional has the level of language proficiency necessary to practise safely.

Patient and public engagement

55. The 'Common values and principles' statement, set out by Health Ministers in May 2006, makes reference to the patient-centered aims of European healthcare. The protection, promotion and maintenance of the health and safety of the public should be at the heart of good healthcare regulation in Europe. Patients and the public have a key role to play in developing regulatory systems that put patient safety and patient interests at their heart. AURE believes the European Commission should work with regulators to develop models of public and patient engagement

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within European healthcare regulation. By engaging the public in the regulatory process, regulation will be more transparent, better able to serve the needs of the society for whose benefit it operates and command the confidence and support of all interest groups. It is also consistent with the principles of better regulation: accountability, transparency, consistency, targeting and proportionality⁵.

Key Recommendations

56. There should be some common principles across Europe regarding safe and high quality healthcare, in particular regarding fundamental principles of standards and ethics (such as consent and patient confidentiality) that should be embedded in national standards and codes of practice across the EU.

57. Establishing a common ethical framework or code across the EU is unworkable. It is important for Member States to have the flexibility to take different decisions about the care they provide based on local cultural values and circumstances.

58. Healthcare professionals must have good communication skills in order to practise safely and effectively. This requires them to be proficient in the language or languages of the country in which they work. Competent authorities should have the legal ability to test the language competence of all health professionals where their first language is not that of the Member State in which they seek registration.

59. Public and patient engagement in healthcare regulation ensures that the regulatory process is transparent and better able to serve the needs of the society for whose benefit it operates. The European Commission should promote public and patient engagement as good practice in healthcare regulation.

⁵ Principles of Good Regulation set out by the UK's Better Regulation Commission.



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Annex

EEA registrations (excl. UK) with UK health regulators 2003-2006

Competent Authority	2003	2004	2005	2006
General Medical Council	1770	2419	2340	3076
Nursing and Midwifery Council	1030	1193	1753	N/A
Royal Pharmaceutical Society of Great Britain	441	271	432	N/A
General Chiropractic Council	N/A	N/A	1	2
General Dental Council	268	661	1,136	N/A
Health Professions Council	1200	1548	1800	1164
General Optical Council	12	17	11	27