
GMC Position Paper **Draft Directive on the application of** **patients' rights in cross border healthcare in Europe**

September 2008

Introduction

1. The General Medical Council (GMC) is the independent regulator for doctors in the UK. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.
2. There are currently almost 250,000 doctors on the UK Medical Register. 22,415 (9.0%) of these doctors qualified in other parts of the European Economic Area.
3. The law gives the GMC four main functions:
 - keeping up-to-date UK registers of qualified doctors
 - fostering good medical practice in the UK
 - promoting high standards of medical education in the UK
 - dealing firmly and fairly with doctors practising in the UK whose fitness to practise is in doubt.
4. Our approach to medical regulation stresses the importance of professionalism in raising healthcare standards and subsequently reducing risks to patients. We believe that the development of this approach to medical regulation across Europe could make a significant contribution to safe and high quality healthcare in the context of patient rights in cross-border healthcare.
5. We set out below how this could be secured within the Directive on the application of patient rights on cross-border healthcare. For more information please contact:

Claire Herbert
Head of European & International Development
General Medical Council
350 Euston Road, London
UNITED KINGDOM NW1 3JN
tel: + 44 20 7189 5042 email: cherbert@gmc-uk.org

Summary

Assuring safe and high quality healthcare

6. The Directive must support strong and effective patient-safety-centred national medical regulation that promotes high standards of healthcare and professional practice across Europe.

- We believe that professional and ethical standards for high quality medical practice must be developed at national or regional level and have patient safety at their heart.
- We do not believe there is a role for the European Commission in the setting of professional and ethical standards in medicine and the Directive must not provide for this.
- The Directive should make the development of a national or regional system of performance enhancement and assessment mandatory for all doctors at regular intervals.

The patient's right to effective medical regulation

7. The Directive must ensure that all patients accessing healthcare in another European member state have access to information about medical regulation, and to fair, transparent and efficient regulatory redress in the case of suffering harm arising from impairment or professional misconduct.

- Regulatory responsibility in the context of patient mobility must reside with the 'member state of treatment' – this must be clearly set out in the Directive.
- The Directive must provide for regulators to supply information to patients about registered medical practitioners; regulatory processes and procedures; the standards to which doctors must practise; and notifications of disciplinary hearings and findings.
- Responsibility for the provision of information about the regulatory system should rest with the 'member state of treatment'.

Information exchange between regulators

8. Patients need assurance that all doctors are fit and safe to practise in the context of both patient and professional mobility. The Directive must bring about enhanced communication, cooperation and information exchange between medical regulators.

- The Directive must contain a specific duty upon national authorities to reactively and proactively exchange regulatory information about doctors in the interests of patient and public safety.

Promoting the principles of good medical regulation

9. The Directive must bring certainty of medical regulatory responsibility in all forms of cross-border healthcare, ensuring proportionality and accountability.

- National medical regulators must only take regulatory responsibility for those doctors physically located in their jurisdiction.
- The role of the proposed Implementing Committee (Article 19) must be defined in the Directive.

GMC Position

10. The Directive on the application of patients' rights in cross-border healthcare must provide for the patient's right to effective medical regulation. This should encompass: patient-safety-centred medical regulation across Europe; transparent national and/or regional regulatory processes and information for patients, the public, professionals and regulators; efficient and proactive professional regulatory collaboration; and high safety and quality standards set at national and/or regional level.

11. This paper sets out the GMC's position on the draft Directive:

Assuring safe and high quality healthcare

12. The standards, role and practice of medical practitioners cannot be decoupled from quality and safety concerns across all healthcare provision. Nor can assurances for patients and the public, about the fitness to practise of doctors based in other European Member States, be distinguished from those required for doctors who choose to exercise their rights of free movement. They are in principle the same doctors.

13. All patients in Europe must have the assurance that the doctors that treat them – whether at home or abroad – are practising in accordance with robust professional and ethical standards. These include relating to quality, professionalism, confidentiality, continuity of care, and the communication of patient records.

14. It is also important that professional and ethical standards are developed at the national or regional level in order to take account of cultural and practical considerations.

15. Our professional guidance, *Good Medical Practice* – which has been developed in the context of a wide range of UK stakeholder groups, is increasingly embedded in health service delivery in the UK. We do not believe the setting of professional standards at European level is of added value. It could result in greater risk to patients through the application of “lowest common denominator” standards, to the detriment of safe and high quality healthcare.

16. It is inevitable that as a doctor moves through his/her career their practice changes. Sometimes they may have difficulty in continuing practising in accordance with the standards that are expected of them. There should be mechanisms in all Member States to enable the regular evaluation of a doctor’s practice in order to assure patients that they continue to be competent to practise.

17. The GMC is working on plans to change the way doctors in the UK are regulated to practise medicine, in the form of licensing and revalidation. This will be the single biggest change to medical regulation since the establishment of the GMC 150 years ago.

18. The first change will come in late 2009 when the GMC will introduce licences to practise. All doctors in the UK will be required by law to hold a licence if they wish to exercise the legal privileges currently reserved for registered medical practitioners (such as prescribing medication and signing death certificates). Licences to practise will require periodic renewal. At the end of the first revalidation cycle, the licence to practise will signify that the GMC has received positive affirmation that a doctor remains up to date and fit to practise.

19. All doctors holding a licence to practise will need to participate in revalidation. This means they will need to collect evidence about their practice to support their future revalidation such as undergoing an annual workplace appraisal, and participating in an independent process for obtaining feedback from patients (where applicable) and colleagues.

20. The purpose of this new approach is to give patients assurance that licensed doctors are up to date and fit to practise. Revalidation is not only designed to find doctors whose fitness to practise is impaired. It is designed to promote excellence in clinical practice and, through supporting the professional development of doctors, enhance patient safety.

21. Medical Revalidation in the UK could become a model of good practice for medical regulators across the European Union. We believe all regulatory jurisdictions should develop similar approaches to provide assurance to patients, the public, and other regulators of doctors’ continued competence to practise.

The GMC believes that professional and ethical standards for high quality medical practice must be developed at national or regional level and have patient safety at their heart.

We do not believe there is a role for the European Commission in the setting of professional and ethical standards in medicine and the Directive must not provide for this.

The Directive should make the development of a national or regional system of performance enhancement and assessment mandatory at regular intervals.

The patient's right to effective medical regulation

22. The focus of the draft Directive is the patient's right to access treatment in another member state and the right to safe and high quality healthcare for all patients. Alongside this must sit a right for patients to effective, fair and robust medical regulation – whether the patient is treated at home or abroad. Regulatory responsibility must rest with the 'member state of treatment'.

23. The nature and approach to medical regulation in Europe differs from jurisdiction to jurisdiction. A patient's healthcare experience in another European member state and the process for regulatory redress if things go wrong, may not be the same as at home.

24. There must be greater regulatory transparency across Europe for patients, the public, professionals and other regulators.

25. In the UK, we have a freely accessible web-based real-time list of registered medical practitioners – patients can check anytime that the doctor treating them is registered and has no disciplinary action against them. We make our standards and guidance freely available to the public via our website and on request, and we set out on our website the mechanism for making complaints about a doctor and notifications of disciplinary hearings.

26. We are also about to launch *Patients' help* - an interactive site which helps patients in the UK to understand which organisation to complain to if they have concerns about their doctor. It enables users to listen to a range of case studies, view an 'at a glance' chart on the life cycle of a complaint and look up local contact details on an interactive map.

27. While promoting transparency and access to information, the Directive must not impose any disproportionate administrative burdens on medical regulators, particularly if in reality there will only be small numbers of patients exercising their right of free movement to access healthcare in another European Member State.

28. Patients must be able to access information by the most authoritative means and we believe this should be from the prospective member state of treatment.

Regulatory responsibility in the context of patient mobility must reside with the member state of treatment – this must be clearly set out in the Directive.

The Directive must provide for regulators to supply information to patients about registered medical practitioners; regulatory processes and procedures; the standards to which doctors must practise; and notifications of disciplinary hearings and findings.

Responsibility for the provision of information about the regulatory system should rest with the ‘member state of treatment’.

Information exchange between regulators

29. For some time we have called on the European Commission to introduce a legal duty on all medical regulators to share registration and fitness to practise information proactively with other regulators in Europe.

30. In all circumstances this is important to ensure that doctors, exercising their rights of free movement, are only granted registration when they are known to be fit and safe to practise. It is also important when doctors are simultaneously registered in more than one European regulatory jurisdiction. If information is not shared efficiently and effectively a doctor could, unwittingly for the regulator, be erased or suspended in one jurisdiction while continuing to practise and potentially harm in another.

31. The European Parliament has already agreed with us on the need to establish a legal duty on information exchange. The Parliament called for this in both the ‘resolution of 15 March 2007 on Community action on the provision of cross-border healthcare <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2007-0073+0+DOC+WORD+V0//EN&language=EN>’ and in the ‘resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (2006/2275(INI)) <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2007-0201+0+DOC+WORD+V0//EN&language=EN>’

32. The Directive must introduce a legal duty on national and regional regulatory authorities to reactively and proactively exchange registration and disciplinary information about the doctors their register.

The Directive must contain a specific duty upon national authorities to reactively and proactively exchange regulatory information about doctors in the interests of patient and public safety.

Promoting the principles of good medical regulation

33. Medical regulation in Europe must appropriately comply with the principles of good regulation. In this regard regulation should be targeted, proportionate, accountable, consistent and transparent. It should also take place at the level most able to maintain patient safety and to deal firmly and fairly with doctors whose practice falls short of expected standards.

34. There should be no ambiguity as to where regulatory responsibility rests in any case of cross-border healthcare. In particularly complex situations, such as e-health, where neither the patient or professional physically moves, there must be clarity as to who holds regulatory responsibility.

35. The GMC cannot hold regulatory responsibility for doctors who are not on the UK Medical Register. It must be the responsibility of contracting bodies to assure themselves that any e-health contractors are appropriately registered and qualified in the country from which they are practising.

36. Furthermore there should be no ambiguity as to the role of the European Commission in relation to medical regulation. The role of the 'Implementing Committee', proposed in the draft Directive, should be defined and limited in law to avoid future disproportionate, unanticipated and inappropriate spill-over into the national regulatory role.

National medical regulators must only take regulatory responsibility for those doctors physically located in their jurisdiction.

The role of the proposed Implementing Committee (Article 19) must be defined in the Directive.

Conclusion

37. The GMC believes the fundamental purpose of medical regulation is to ensure safety and quality of care for patients. Our approach to regulation is based on the fostering of professionalism. We believe that greater professionalism will drive up clinical standards and contribute to continuous improvement in patient safety. This makes effective regulation a vital component in achieving safe and high quality healthcare for all across Europe.

38. The GMC will work closely with the European institutions, the UK Government, other UK and European regulators, and stakeholder groups Europe-wide, to work to ensure the issues outlined in this briefing are taken into account throughout the legislative process.

An abridged version of this position paper has been submitted as written evidence for the Inquiry into the European Commission's proposed directive on the application of patients' rights in cross-border healthcare to Sub-Committee G (Social Policy & Consumer Affairs) of the House of Lords Select Committee on the European Union.